



January 28, 2020

**Re: EPA Subpart O ARV and SCV Compliance Test
Report**

To: **Rubén Martínez Vargas**

Customed Quality Assurance Director

Customed

ruben.martinez@prhospital.com

Call Box 158

Carolina, P.R. 0098-0158

787-622-5151 * 7634

Dear Mr. Vargas:

Attached is one copy of the final test report for the above referenced testing program. We understand that you will submit the required copies of this report to the Puerto Rico Environmental Quality Board for review. Should there be any questions concerning the enclosed report, please contact me at (484) 252-4335.

Respectfully,

L. Christopher Heilner

L. Christopher Heilner

Owner, LCH Consulting Associates, LLC

Final Test Report
2019 for Destruction Removal Efficiency of Ethylene Oxide Emissions from
Sterilization Chamber Vents and Sterilization Aeration Room Vents

Puerto Rico Hospital | Customed
7 Igualdad Street
Fajardo Puerto Rico 00738
January 28, 2020

Prepared for:
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For submittal to:
Puerto Rico Environmental Quality Board

Prepared by:
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CERTIFICATION OF ACCURACY AND COMPLETION

I, Mr. L. Christopher Heilner, as the LCH Consulting Associates report author, certify under penalty of law that I believe the information provided in this document is true, accurate and complete. I am aware that there are significant civil and criminal penalties, including the possibility of fine or imprisonment, or both, for submitting false, inaccurate, or incomplete information.

Signed: L. Christopher Heilner Date: 01/28/2020

L. Christopher Heilner
Owner
LCH Consulting Associates
Telephone: (484) 252-4335

1.0 EXECUTIVE SUMMARY

This stack test report aims to satisfy Customed's PREQB permit and EPA Subpart O requirements. LCH Consulting Services, LLC (LCH) of Pottstown, Pennsylvania, was retained to perform the compliance stack test and this resulting final test report. The following provides contact, facility, permit, and source information:

1.1 CONTACT SUMMARY

Facility (Customed) Responsible Official

Rubén Martínez Vargas

Customed Quality Assurance Director

Customed

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1.2 PERMIT AND SOURCE SUMMARY

1.2.1 Applicable Regulation – 40CFR63.360 Subpart O: Ethylene Oxide Emissions

Standards for Sterilization Facilities

PREQB Permit Number	XXXX
LCH Project Number	P101419
Process Description	Commercial Ethylene Oxide sterilization facility including pre-conditioning, exposure and aeration of medical products
Emission Points	<p>EP1 Sterilization Chamber Vent</p> <ul style="list-style-type: none">• Chamber 1 1212.8 ft³ usable volume using 43-60 pounds EtO per cycle <p>EP2 Aeration Room Vent</p> <ul style="list-style-type: none">• 14 Pallet Aeration Room
Control Devices	<p>Advanced Air Technologies SN021126 Acid Gas Scrubber</p> <ul style="list-style-type: none">• SCV EP1 Controlled by scrubber• Liquor is 10% H₂SO₄/40% Ethylene Glycol• Liquor pH is monitored and was 0.45 at time of testing• Reaction Tank 1 was 72.2" at time of testing• Reaction Tank 2 was 17.0" at time of testing
Control Efficiency	99% removal or less than 1ppm for Subpart O compliance
SCV (E1) ARV (E2)	<ul style="list-style-type: none">• 2 sample runs during the chamber's simultaneous first evacuations for SCV• Empty chamber with normal maximum EtO loading for SCV test 1• Chamber with product and normal cycle for SCV test 2

- 3 sixty minute sample runs for ARV after 14 pallets of product in aeration for 60 minutes

Test Methods

40CFR60 Appendix A

- Method 1 – Determination of Sampling Locations
- Method 2 – Volumetric Flow Rate Determination of Stack Gases
- Method 3 – Molecular Weight Determinations of Stack Gases
- Method 4 – Determination of Stack Gas Moisture Content (Saturation by Psychometric Chart)
- Method 18 – EtO by gas chromatography – integrated bag sample, on-site gas chromatography, flame ionization detector (FID)
- Subpart O 40CFR63.365(b) calculations

Test Dates

January 9th and 10th of 2020

Table 1 SCV Subpart O Results

Table 1 – Summary of Results SCV1 Destruction Removal Efficiency Advanced Air Technology Scrubber SN 021126 Customed, Inc. Fajardo, Puerto Rico January 9th, 2020									
Run	Date	Chamber	Mass EtO Charged to Chambers (pounds)	Percent Chamber Gas Evacuated (%)	Scrubber Outlet Gas Volume (dscf)	Scrubber Outlet EtO Concentration (ppm)	Mass of EtO at		DRE (%)
							Scrubber Inlet (pounds)	Scrubber Outlet (pounds)	
1	1/9/2020	1	43.0	63.92%	205.0	12.5	27.49	0.00029	99.9989%
2	1/9/2020	1	60.4	63.98%	240.6	16.2	38.64	0.00044	99.9988%
Average Removal Efficiency								99.9989%	

Table 2 ARV Subpart O Results

Table 2 - Summary of Results ARV Emissions Advanced Air Technology Dry Bed Scrubber Customed, Inc. Fajardo, Puerto Rico January 9th, 2020				
Run	Date	Start Time	Time End	Outlet Concentration (PPM)
1	1/9/2020	21:03	22:03	0.410
2	1/9/2020	22:07	23:07	0.637
3	1/9-10/2020	23:11	00:11	0.616
average				0.555

2.0 PROCESS DESCRIPTION

Chamber 1 manufactured by Vacudyne is used to sterilize medical products. The chamber was advanced to “sterilant removal” phase to create a worst-case scenario to challenge Customed’s AAT scrubber system. The in-chamber sterilization cycle includes pre-conditioning, sterilization and aeration. The typical cycle for sterilization includes four vacuum and nitrogen injection pulses to remove air, injection of clean steam for humidification, ethylene oxide charge, injection of additional nitrogen, three nitrogen washes i.e. evacuations all of which are vented to the Scrubber system. Process run records are available in Attachment F.

The Customed scrubber system provides pollution control with an exothermic reaction between ethylene oxide and sulfuric acid. The scrubber consists of a reaction tank, spray nozzles, demister pad and a packed tower. Scrubber pH, glycol and reaction tank levels were monitored before and after the test program. Scrubber process data was collected by Scrubber and is available in Attachment F.

Sterile product is transferred to the aeration room for the final degassing. The aeration room vent (ARV, EP2) is controlled by an Advanced Air Technologies Safe Cell II dry bed scrubber. The system uses media beads to scrub the ethylene oxide from atmospheric emissions. 14 pallets of product were transferred after the second SCV test cycle. The product was in aeration for sixty minutes prior to starting the emissions tests.

3.0 SCOPE AND OBJECTIVES

The objective of the testing program was to satisfy the EQB permit for ongoing compliance of the existing dry bed ARV scrubber and to determine scrubber performance existing SCV scrubber.

The performance of the scrubber system was determined by testing the sterilization chamber vent. The highest concentration at the abator occurs at the start of the initial evacuation. The test procedures of 40CFR63.365 (b) are suitable to demonstrate the compliance status of the Scrubber. 63.365(b) reads: *“Efficiency at the sterilization chamber vent. The following*

procedures shall be used to determine the efficiency of all types of control devices used to comply with 63.362(c) sterilization chamber standard.”

Subpart O was written based on technologies that destroy ETO immediately as it is exhausted from the chamber. With the scrubber system, ETO enters the packed tower and scrubber liquor is sprayed over packing material and circulated through the reaction tanks. As per Subpart O, the greatest ETO concentrations are emitted from the first evacuation of the sterilization chambers. Volumetric flow was determined on a minute basis from the beginning of the first evacuation until the completion of the final evacuation. This was between 8 and 11 minutes. Moisture was reported as saturated at the Scrubber balance outlet temperature.

EPA test methods strive to demonstrate performance under a worst case scenario. The facility operated at normal maximum loading for the performance test. Customed used a cycle with no product in the chamber and sampling only pre-aeration cycle phases are the most conservative in terms of loading as there is no product mass or product packaging to retain ETO. This results in more ETO coming from the first purge cycle as compared to a cycle with product present. The second SCV test was performed with product in the chamber. This condition yielded very similar results and allowed Customed to continue commercial operations during testing.

4.0 FIELD TESTING PROGRAM

4.1 Testing Location and Traverse Points

Sampling for the SCV was conducted at the outlet of the scrubber. The location was accessed via manlift and crane. One port was used, single point traverse was used. The nature of the process does not allow flow except for chamber releases. Timing of the processes did not allow for a traverse or cyclonic flow check determination. The stack inside geometry was determined for Method 1 compliant single point sampling locations. This point of average velocity was used for flow determinations during each sampling run. This data is available in Attachments E.

Sampling for the ARV was conducted at the outlet of the AAT dry bed scrubber. Only concentrations of ethylene oxide were determined and reported at the ARV.

4.2 Testing Summary

Testing was conducted according to the U.S. EPA Federal Register 40 CFR 60 Appendix A. The following procedures were utilized at the SCV scrubber exhaust stack.

Procedures¹

- Method 1: Sample and Velocity Traverses for Stationary Sources
- Method 2: Determination of Stack Gas Velocity and Volumetric Flow Rate
- Method 3: Determination of Stack Gas Molecular Weight
- Method 18: Volatile Organic Compounds by Gas Chromatography

Two test runs were performed for each emission parameter. Some emission parameters where possible, were determined concurrently. All test runs include concurrent gas flow rate determinations by EPA Methods 1, 2, and 3. Regarding Method 3 sampling, the option to use the molecular weight of 30.00 for test parameters as the chamber atmosphere is essentially ambient air heated with steam was used.

Gas flow rate determined by EPA Methods 1, 2, and 3 concurrently with emissions sampling were used to calculate lb/hr emission rates. This information available in Attachment E.

The average of the two test runs were compared to the allowable emission limits to determine compliance.

Detailed descriptions of the sampling trains, analyzers, and procedures are provided in Section 4.4.

Equations that will be used for test calculations are presented in Attachment A.

¹Source: U.S. EPA, *Federal Register*, Title 40 Part 60, Appendix A

4.3 PROCESS OPERATIONS AND EMISSION TESTING

During each sample run the following process data were confirmed

1. Scrubber pH, Glycol Percentage and Reaction Tank Level
2. Amount of Ethylene Oxide Charged
3. Sterilization Cycle Parameters
4. Sterilization Chamber Conditions

This information is available in Attachments F and G.

4.4 SAMPLING PROCEDURES

The following sections provide descriptions of sampling procedures and the sampling trains that were used for emissions testing.

4.4.1 Gas Flow and Temperature Measurements

Gas Flow Measurement were made with Standard Pitot (velocity) tube connected to an inclined manometer and digital pressure transducers. The static pressure was measured using the same Pitot tube and manometer. A Chrome-Alumel thermocouple attached to a digital indicator was used to measure the gas temperature at each traverse point.

This information can be found in Attachment E.

4.4.2 Oxygen and Carbon Dioxide Emission Concentration Determinations

Oxygen (O_2) and carbon dioxide (CO_2) emission concentrations could be determined by EPA Method 3 *Determination of Oxygen and Carbon Dioxide Concentrations in Emissions from Stationary Sources*. Oxygen and CO_2 emission concentrations were used primarily for the determination of gas molecular weight required for gas flow rate calculations. For this reason, we did not perform any actual molecular weight determinations and Method 3 was used to assign a molecular weight of 30.00, which is thought to be appropriate as this is essentially thermoelectrically heated air. Molecular weight will be the same at the inlet and the outlet and thus cancel each other out for destruction efficiency calculations.

4.4.3 Determination of Ethylene Oxide Emissions

Procedures outlined in 40 CFR 60 Methods 18 and Subpart O 40CFR63.365 (b) calculations will be used to determine Ethylene Oxide emission concentrations, and are discussed as follows:

SCV ETO samples were collected and analyzed using the Integrated Bag Sampling and analysis procedure of Method 18 section 8.2.1.1. An un-heated Teflon sample line and stainless-steel sample probe was placed in the scrubber outlet stack connecting to a Teflon line to a 100% Teflon (new sample bags were employed for each sample) sample bag inside a rigid stainless steel evacuated canister. A sample rate of approximately .25 liters per minute was established and the sampling system was purged without a bag in line for as long as possible prior to sampling. A bag was installed immediately prior to sampling and the sample was collected by evacuated canister technique over the duration of the entire first evacuation of the four chambers used for testing purposes.

ARV ETO were collected using the direct interface procedure of Method 18. A Teflon sample line was connected to a Teflon pump to extract a sample from ARV AAT outlet at approximately 20LPM. A slip stream of .25LPM was introduced to the GC sampling valve for continuous integrated sampling. Three sample runs of sixty minutes each and 14 to 16 three minute chromatograms were performed. Prior to sampling a direct interface recovery study was performed, available in table 4. After both SCV and ARV sampling a calibration drift assessment was performed available in table 3.

4.5 SAMPLE ANALYSES

All samples were analyzed onsite by L. Christopher Heilner of LCH operating a GC FID. All QA/QC measures inherit to the analyzer and the methodology were followed.

4.5.1 GC Description

Samples were analyzed by gas chromatography using an SRI 8610C gas chromatograph with dual column, dual detector (PID and FID) with heated sample loops, injectors and 3 meter packed columns. Gas in the sample loop was injected directly into the GC's analytical columns

by the gas sampling valve. The GC was operated with carrier gas flow of 18 ml/minute and column temperature of 130°C. The carrier gas was ultra-high purity helium. Hydrogen and air were used to maintain the FID. ETO eluted at approximate 0.8-0.9 minutes.

4.5.2 Calibration Standards

Three cylinders of calibration standard, ETO in nitrogen, in concentrations of 1000.0, 100, 10 and 1 ppm were used to create an FID calibration curve to calculate ETO concentration in ppm given instrument response in millivolts. Calibration standards were analyzed in triplicate and the average value of the samples will be calculated. An analytical result was considered valid if its value is within 5% of the average value. Calibration curves are found in Attachment B. Calibration standard certificates are found in Attachment H.

A calibration curve was generated using Microsoft Excel chart function by constructing a linear XY-Scatter graph that solves the quadratic equation of the line $Y=mX+b$ where “y” is the calculated concentration of EtO, “x” is the instrument response, “m” is the constant and “b” is the y-coordinate intercept. The option forcing the graph through zero was enabled so “b” = zero. The least squared R^2 value and the equation of the line was shown. An R^2 value of 95% is acceptable according to Method 18. The gas chromatograph routinely exceeds the 95% R^2 value. The GC/FID showed a 99.9999+% R^2 value and a 0.1807 and .1847 (ARV) y-value. This information is found on the calibration curve in Attachment B.

4.5.3 Chromatograms

The chromatogram log sheet is a Microsoft Excel spreadsheet that transposes run information in an easy to read format and provides the calculating capabilities to assess the QA/QC requirements of the method. The chromatograms were logged by the file path directory of the hard drive storage. This information is found in Attachment C.

The chromatograms were automatically printed at the conclusion of each analysis in .pdf format. Each chromatogram includes information identifying the type of analysis, i.e. set up, calibration, sample, recovery study, date and time of analysis, comments, retention time and integrated peak area. The results are in units of millivolts. Field corrections initiated by the operator were not necessary. The chromatograms can be found in Attachment D.

4.5.4 QA/QC Measures

4.5.4.1 Calibration Drift Assessment

The mid-range calibration standard was analyzed at the conclusion of testing and the results were compared to the initial analysis to determine if calibration drift has occurred. A 5% deviation between results is allowable. The SRI gas chromatograph has historically met the 5% criteria. The table below illustrates the results of the calibration drift assessments.

Table 3 Calibration Drift Assessment						
Advance Air Technology Acid Gas Scrubber SCV DRE Test						
Customed, Inc. Fajardo, Puerto Rico						
January 9th, 2020						
Date	Unit Tested	Detector	Concentration EtO Standard (ppm)	Initial Response (millivolts)	Final Response (millivolts)	Calibration Drift (%)
9-Jan	SCV	FID	100	561.3	542.4	3.48%
10-Jan	ARV	FID	10	57.2	56.4	1.40%

4.5.4.2 Direct Interface and Teflon Sampling Bag Recovery Study

The sample from the outlet SCV scrubber was used to perform the sample bag recovery study. The sample was spiked with the 100ppm calibration and analyzed immediately following spiking. The sample was allowed to age for 2 hours and reanalyzed to establish the sample stability in the sampling bag. The results were found to be in compliance and are illustrated in the table below.

TABLE 4 - BAG RECOVERY STUDY AAT Acid Gas Scrubber DRE Test Customed, Inc. Fajardo, Puerto Rico January 9th, 2020							
Test Date	Test Site	Run No.	Calc. Conc. EtO in Bag "u" (ppm)	Initial Spiked Bag EtO Conc. (ppm)	Conc. of Spike Added to Bag "s" (ppm)	Aged Bag EtO Conc. "t" (ppm)	R Value "R"
1/9/2020	Customed	1	12.46	55.48	43.02	55.67	1.00

$$R = (t - u) / s$$

R must fall within 0.7 and 1.3

Where:

R = the average fraction recovered

t = bag concentration after being spiked and allowed to "age"

u = bag concentration before being spiked

s = increase in bag concentration

Prior to sampling from the outlet ARV scrubber, a direct interface recovery study was performed. A bag of 10ppm calibration gas introduced at the inlet of the sampling system and analyzed in triplicate to determine the integrity of the sampling system. The results were found to be in compliance and are illustrated in the table below.

**Table 5 - Direct Interface Sample Train Recovery Study
Lesni CatOx Performance Test
Boston Scientific, Dorado, Puerto Rico
June 13-14, 2019**

Date	Detector	Concentration EtO Standard (ppm)	Instrument Response		Recovery Efficiency (%)
			Cylinder Direct Inject (millivolts)	Direct Interface Sample Train Inject (millivolts)	
9-Jan	FID	10	57.17	57.46	0.50%

ATTACHMENT A

EQUATIONS

Equation 1: Outlet ETO concentrations

$$W_o = (Q * \text{Mol.Wt.} * C) / (10^6 * \text{Mol.Vol.})$$

Where:

W_o	=	Mass of EtO released from abator to atmosphere
Q	=	Total volume of gas at the outlet of the abator (scf)
Mol.Wt.	=	Molecular Weight of ETO 44.05 (lb/lb-mol)
C	=	Concentration EtO in sample (ppmv)
Mol.Vol.	=	Molar volume: 385.32 scf/lb-mol at STP
10⁶	=	Conversation factor for parts per million

Equation 2: Mass Emission Rates

$$Q = T * (1 - B_{ws}) * V_s * A * ((T_{std} * P_s) / (T_s * P_{std}))$$

Where:

T	=	Duration of test in minutes
B_{ws}	=	Water vapor proportion by volume
V_s	=	Stack gas velocity in feet per second
A	=	Cross-sectional area of the stack in SQFT
T_{std}	=	528(°R) - standard temperature
P_s	=	Absolute stack Pressure ("Hg)
T_s	=	Stack Temperature (°R)
P_{std}	=	29.92" Hg - standard pressure

Equation 3: Destruction/Removal Efficiency

$$DRE = [(W_i - W_o)/W_i] * 100$$

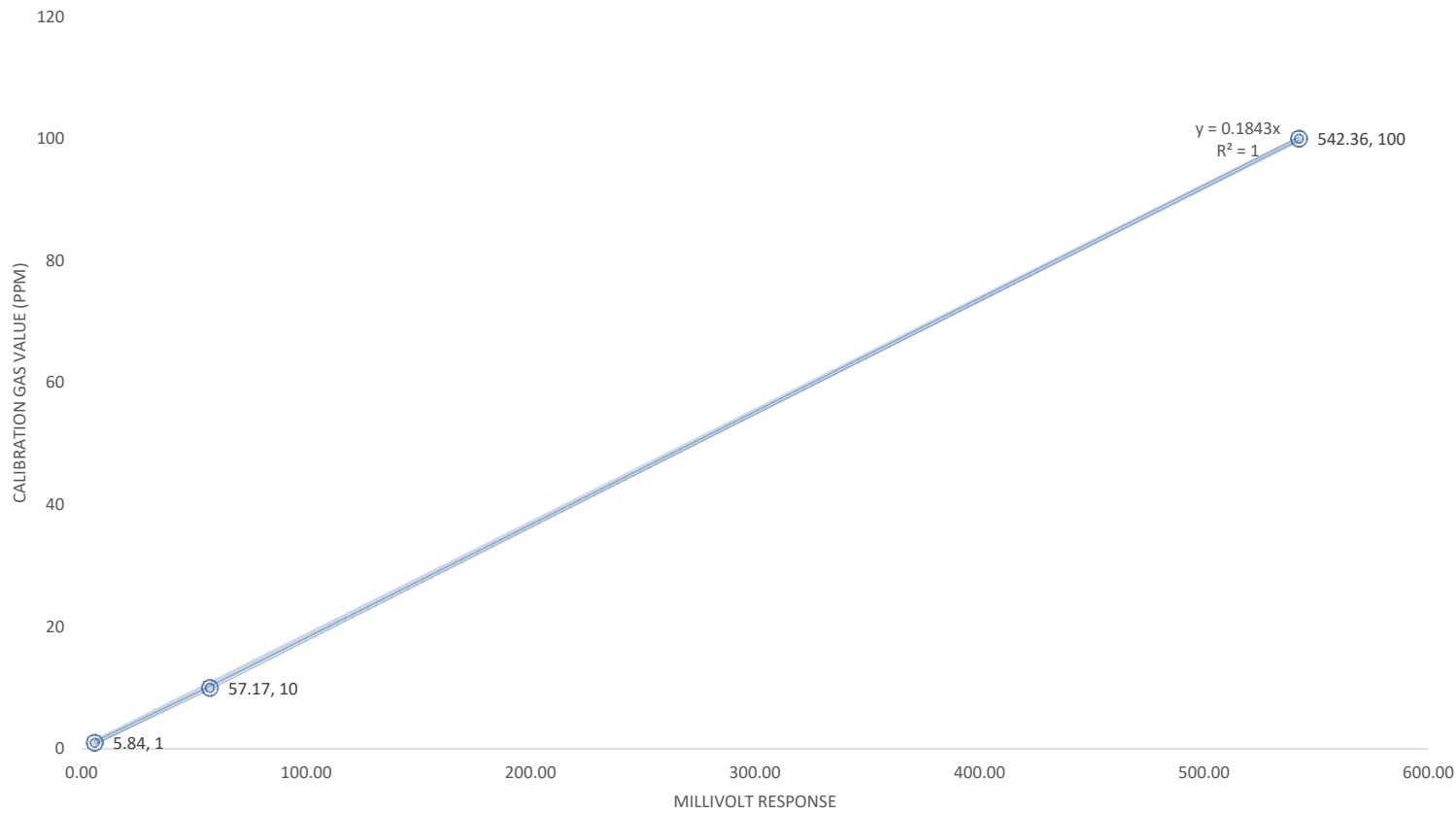
Where:

W_i	=	Mass of EtO at inlet of balance, Subpart O Calculation
W_o	=	Mass of EtO at outlet of the abator

ATTACHMENT B

CALIBRATION CURVES

Customed, Inc., Fajardo, PR - 2019 EPA Subpart O Air Quality Test
Method 18 Calibration Curve - GC FID AAT Dry Bed Scrubber
Removal Efficiency Testing



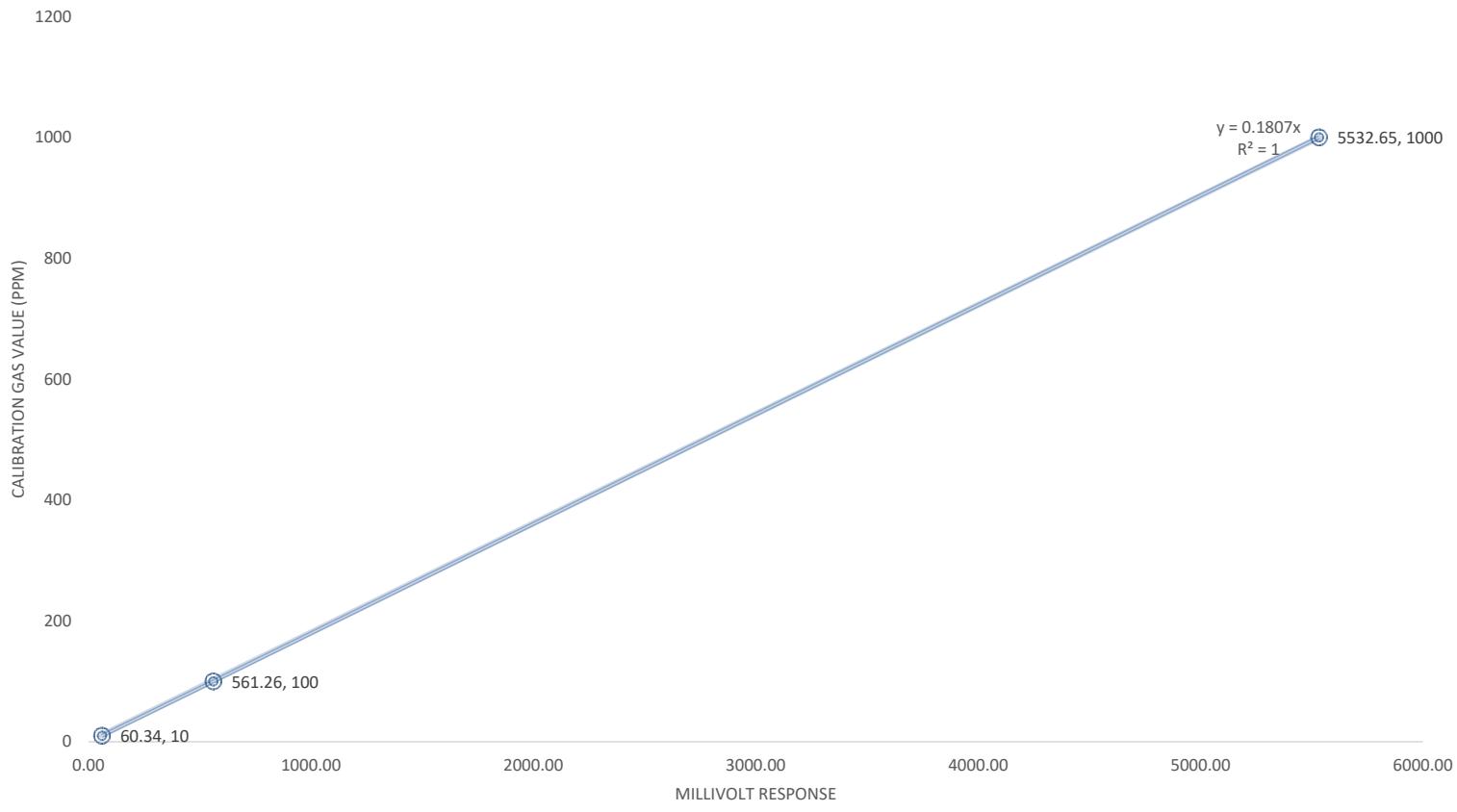
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Customed, Inc., Fajardo, PR - 2019 EPA Subpart O Air Quality Test
Method 18 Calibration Curve - GC FID AAT Acid Gas Scrubber
Removal Efficiency Testing



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ATTACHMENT C

CHROMATOGRAM LOGSHEET

Customed, Inc. Fajardo, Puerto Rico								
Advanced Air Technology Acid Gas Scrubber SCV Subpart O Test								
Chromatogram Logsheet								
Date	fp	type	description	retention time	response	average	score	calc'd conc
01/09/20	840	cal	1000ppm Calibration Gas	0.866	5523.8	5532.65	1.00	1003.2
	843			0.876	5522.2		1.00	
	844			0.863	5552.0		1.00	
01/09/20	859	cal	100ppm Calibration Gas	0.880	563.6	561.26	1.00	101.2
	860			0.880	559.9		1.00	
	861			0.883	560.3		1.00	
01/09/20	873	cal	10ppm Calibration Gas	0.883	60.6	60.34	1.00	10.9
	874			0.883	59.9		0.99	
	875			0.886	60.5		1.00	
01/09/20	881	Sample	Scrubber Test One	0.956	68.5	68.54	1.00	12.5
	883			0.960	68.1		0.99	
	884			0.946	68.9		1.01	
01/09/20	887	Sample	Scrubber Test Two	0.956	89.7	89.56	1.00	16.2
	888			0.970	89.5		1.00	
	889			0.956	89.4		1.00	
01/09/20	891	QA	Recovery Study Initial Scrubber Test 1 Bag Sample Spiked with 100ppm Calibration Gas	0.873	306.1	307.04	1.00	55.5
	894			0.873	306.9		1.00	
	896			0.873	308.2		1.00	
01/09/20	905	Cal	100ppm Calibration Gas Drift Test	0.883	542.3	542.36	1.00	98.0
	906			0.883	542.0		1.00	
	907			0.873	542.8		1.00	
01/09/20	928	QA	Recovery Study Final Scrubber Test 1 Bag Sample Spiked with 100ppm Calibration Gas	0.863	309.8	308.08	1.01	55.7
	929			0.863	307.4		1.00	
	930			0.876	307.1		1.00	

Customed, Inc. Fajardo, Puerto Rico								
Advanced Air Technology Dry Bed Scrubber ARV Subpart O Test								
Chromatogram Logsheet								
Date	fp	type	description	retention time	response	average	score	calc'd conc
01/09/20	905	cal	100ppm Calibration Gas	0.883	542.3	542.36	1.00	99.96
	906			0.883	542.0		1.00	
	907			0.873	542.8		1.00	
01/09/20	914	cal	10ppm Calibration Gas	0.873	57.2	57.17	1.00	10.54
	915			0.873	57.6		1.01	
	916			0.873	56.7		0.99	
01/09/20	919	cal	1ppm Calibration Gas	0.873	5.9	5.84	1.01	1.076
	920			0.866	5.8		0.99	
	921			0.860	5.9		1.01	
01/09/20	936	cal	10ppm Direct Interface Recovery Study	0.873	56.7	57.46	0.99	10.589
	937			0.860	58.0		1.01	
	938			0.873	57.7		1.00	
01/10/20	1220	cal	10ppm Calibration Drift Test	0.863	56.3	56.38	1.00	10.4
	1221			0.863	56.8		1.01	
	1223			0.876	56.0		0.99	
01/09/20	943	ARV Run 1 01/09/20 2103 to 2203		1.116	0.0245			0.00
	944			1.117	0.0045			0.00
	945			1.106	0.0057			0.00
	946			1.146	0.0108			0.00
	947			1.073	0.0710			0.01
	948			0.000	0.0000			0.00
	949							0.00
	950			0.743	4.7220			0.87
	951			0.740	4.0366			0.74
	952			0.736	4.2074			0.78
	953			0.743	3.9635			0.73
	954			0.736	3.8808			0.72
	955							0.00
	956							0.00
	957			0.753	3.7207			0.69
	958			0.750	4.2847			0.79
					2.226			0.410
01/09/20	959	ARV Run 2 01/09/20 2207 to 2307		0.740	3.6765			0.68
	960			0.743	3.5402			0.65
	961			0.743	3.5765			0.66
	962			0.743	3.3196			0.61
	963							0.00
	964			0.743	3.2937			0.61
	965			0.753	3.6320			0.67
	966			0.756	4.0763			0.75
	967			0.753	3.9118			0.72
	968			0.753	3.2680			0.60
	969			0.740	3.8742			0.71
	970			0.746	3.3550			0.62
	971			0.740	3.1113			0.57
	972			0.740	3.0844			0.57
	973			0.740	3.0844			0.57
	974			0.740	3.0760			0.57
					3.459			0.637
01/09/20	975	ARV Run 3 01/09/20 2311 to 0011		0.743	3.7324			0.69
	976			0.743	2.7842			0.51
	977			0.753	2.9044			0.54
	978			0.753	2.8986			0.53
	979			0.750	3.4024			0.63
	980			0.753	3.3888			0.62
	981			0.740	3.4320			0.63
	982			0.740	4.5250			0.83
	983			0.740	3.3899			0.62
	984			0.736	3.3160			0.61
	985			0.736	3.4900			0.64
	986			0.753	3.8158			0.70
	987			0.750	3.0318			0.56
01/10/20	988			0.750	3.1634			0.58
	989			0.753	3.1552			0.58
	990			0.753	3.0843			0.57
					3.345			0.616

ATTACHMENT D

CHROMATOGRAMS

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 07:20:52

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

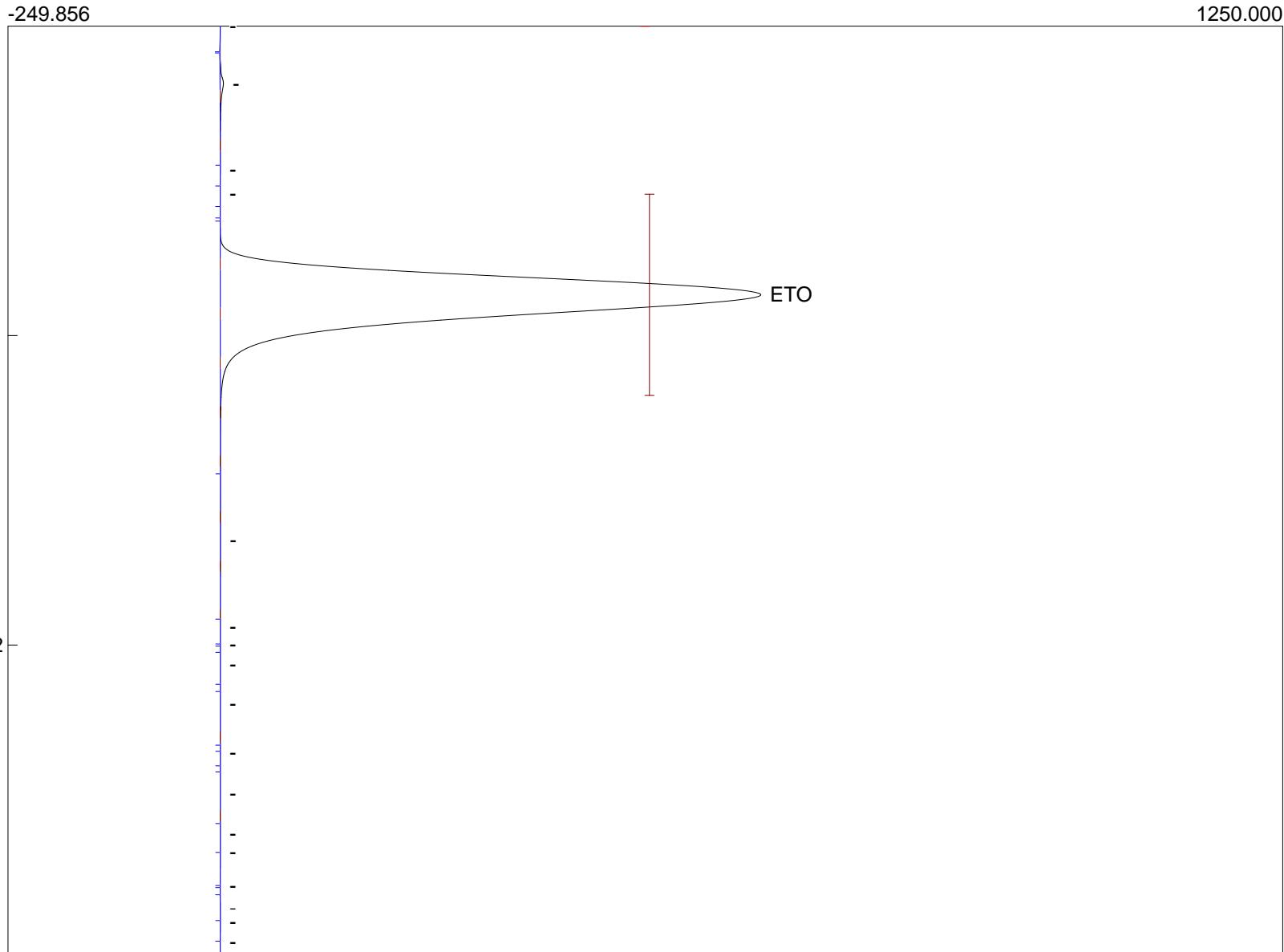
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_840.()

Sample: Sample

Operator: L Christopher Heilner

Comments: 1000ppm Calibration gas



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.866	5523.7774
1			5523.7774

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 07:28:28

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

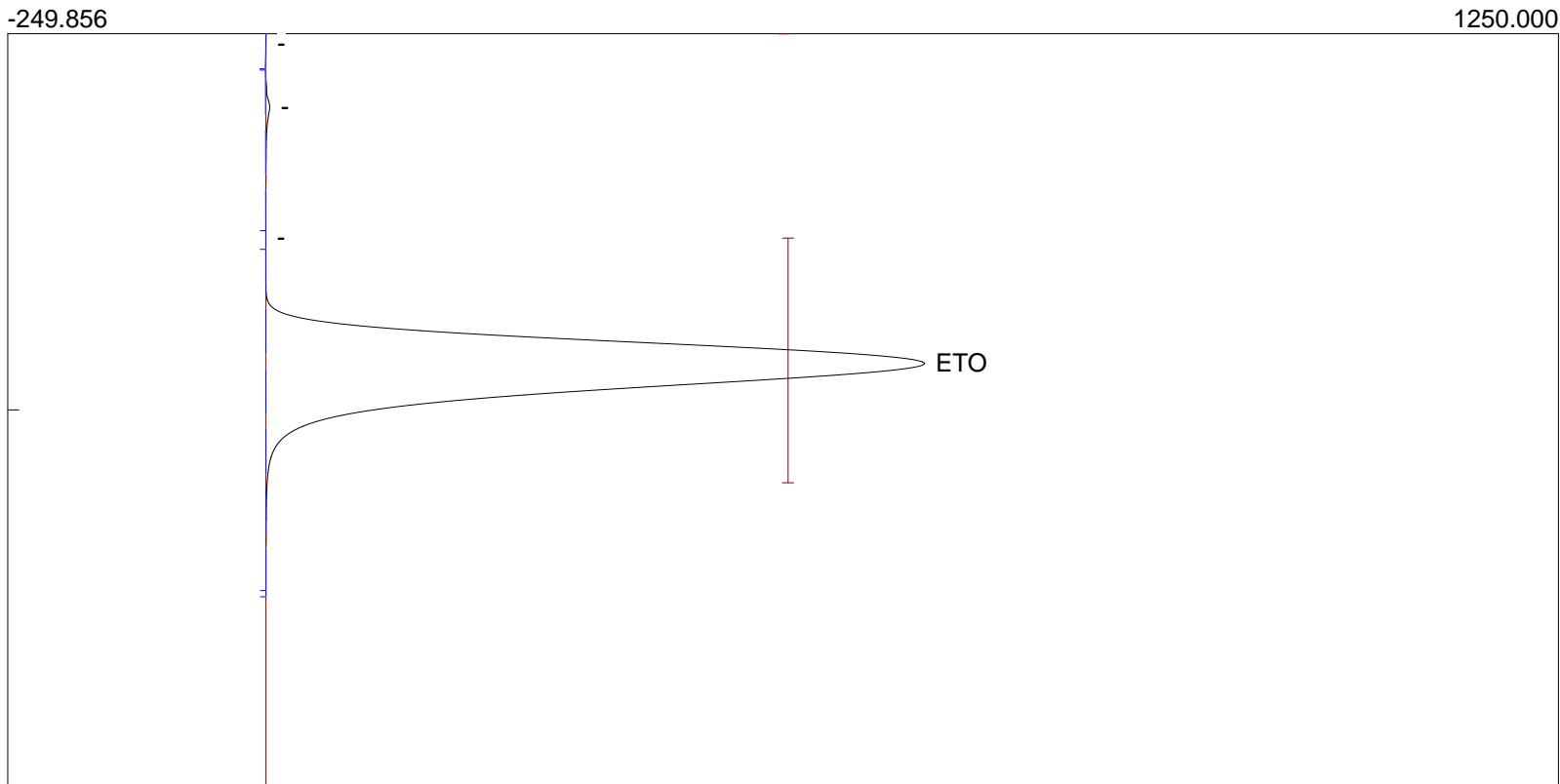
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_843.()

Sample: Sample

Operator: L Christopher Heilner

Comments: 1000ppm Calibration gas



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.876	5522.1816
1			5522.1816

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 07:30:05

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

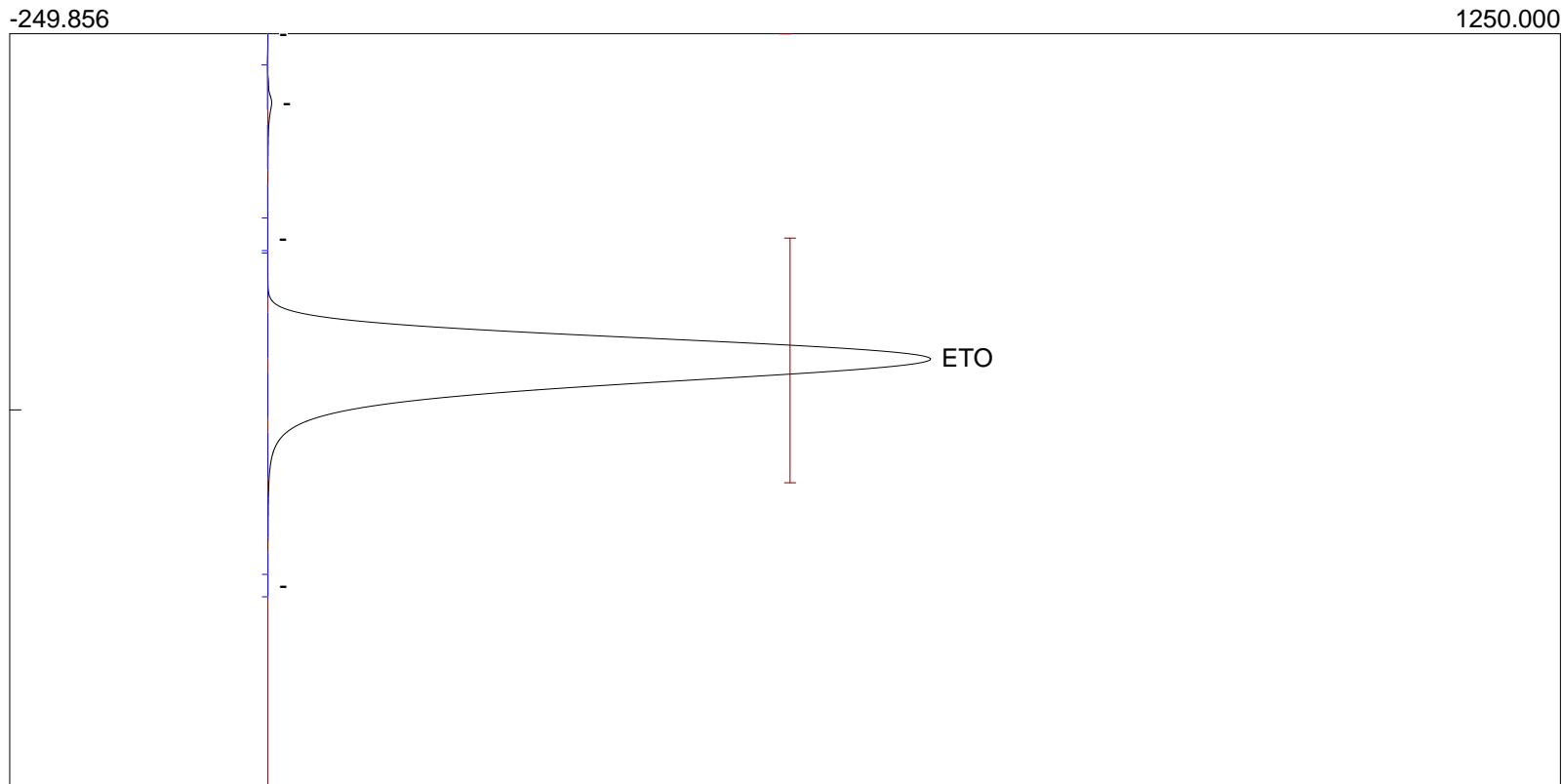
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_844.()

Sample: Sample

Operator: L Christopher Heilner

Comments: 1000ppm Calibration gas



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.863	5551.9872
1			5551.9872

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 07:57:09

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_859.()

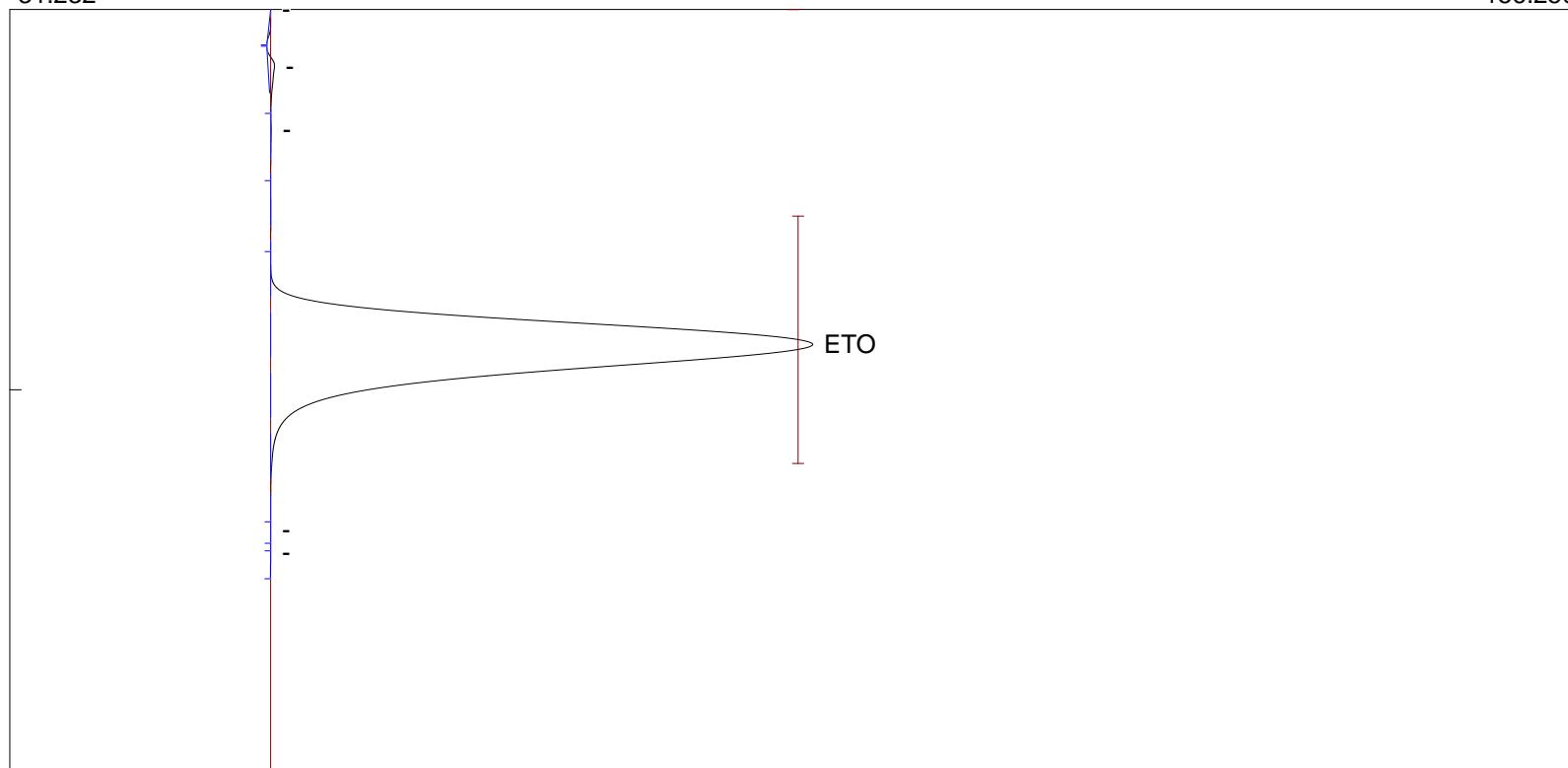
Sample: Sample

Operator: L Christopher Heilner

Comments: 100ppm Calibration gas

-31.232

156.250



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.880	563.6214
1			563.6214

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 07:58:45

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_860.()

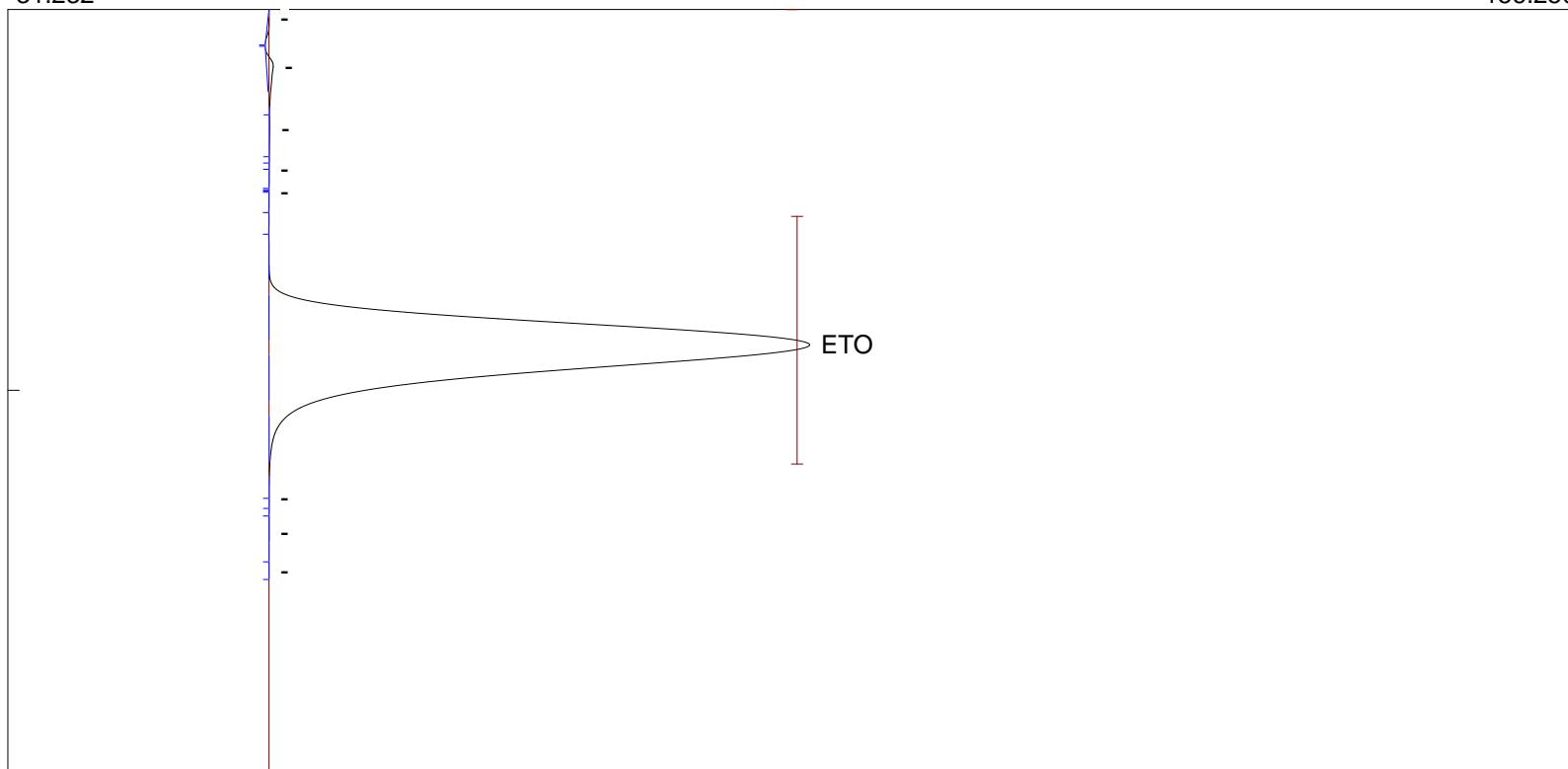
Sample: Sample

Operator: L Christopher Heilner

Comments: 100ppm Calibration gas

-31.232

156.250



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.880	559.8958
1			559.8958

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 08:00:32

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_861.()

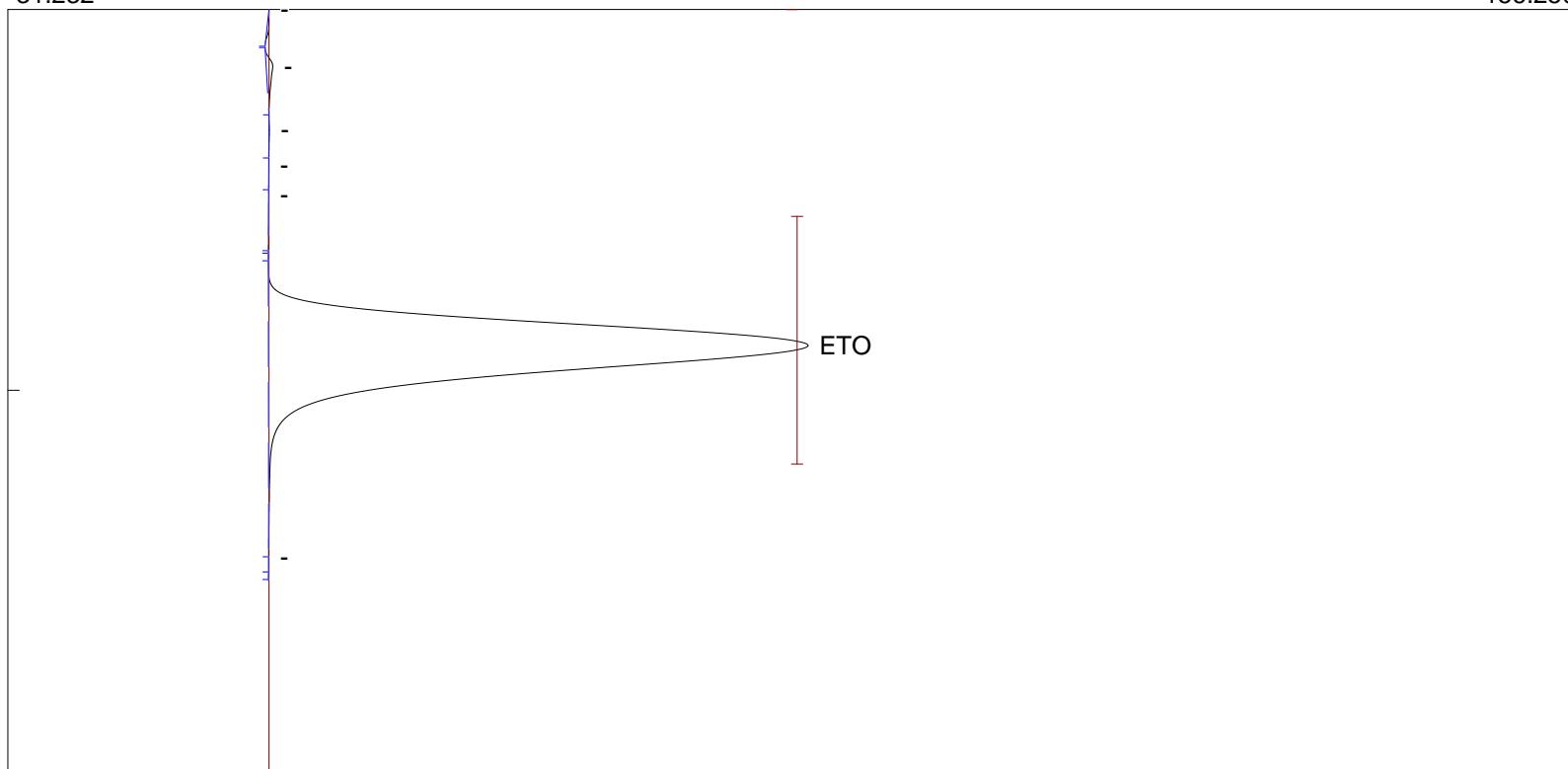
Sample: Sample

Operator: L Christopher Heilner

Comments: 100ppm Calibration gas

-31.232

156.250



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.883	560.2599
1			560.2599

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 08:23:44

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_873.()

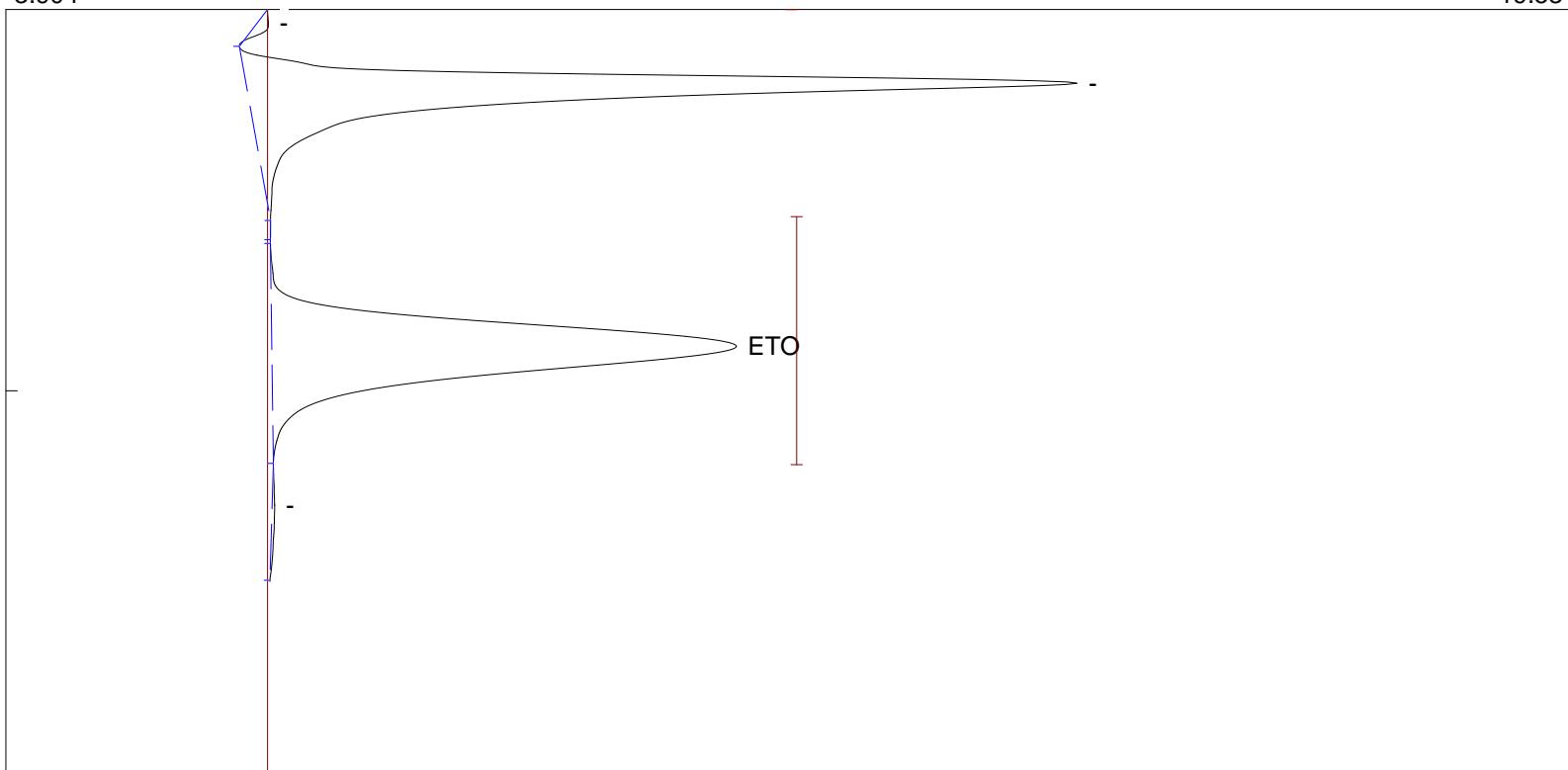
Sample: Sample

Operator: L Christopher Heilner

Comments: 10ppm Calibration gas

-3.904

19.531



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.883	60.6194
1			60.6194

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 08:25:17

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_874.()

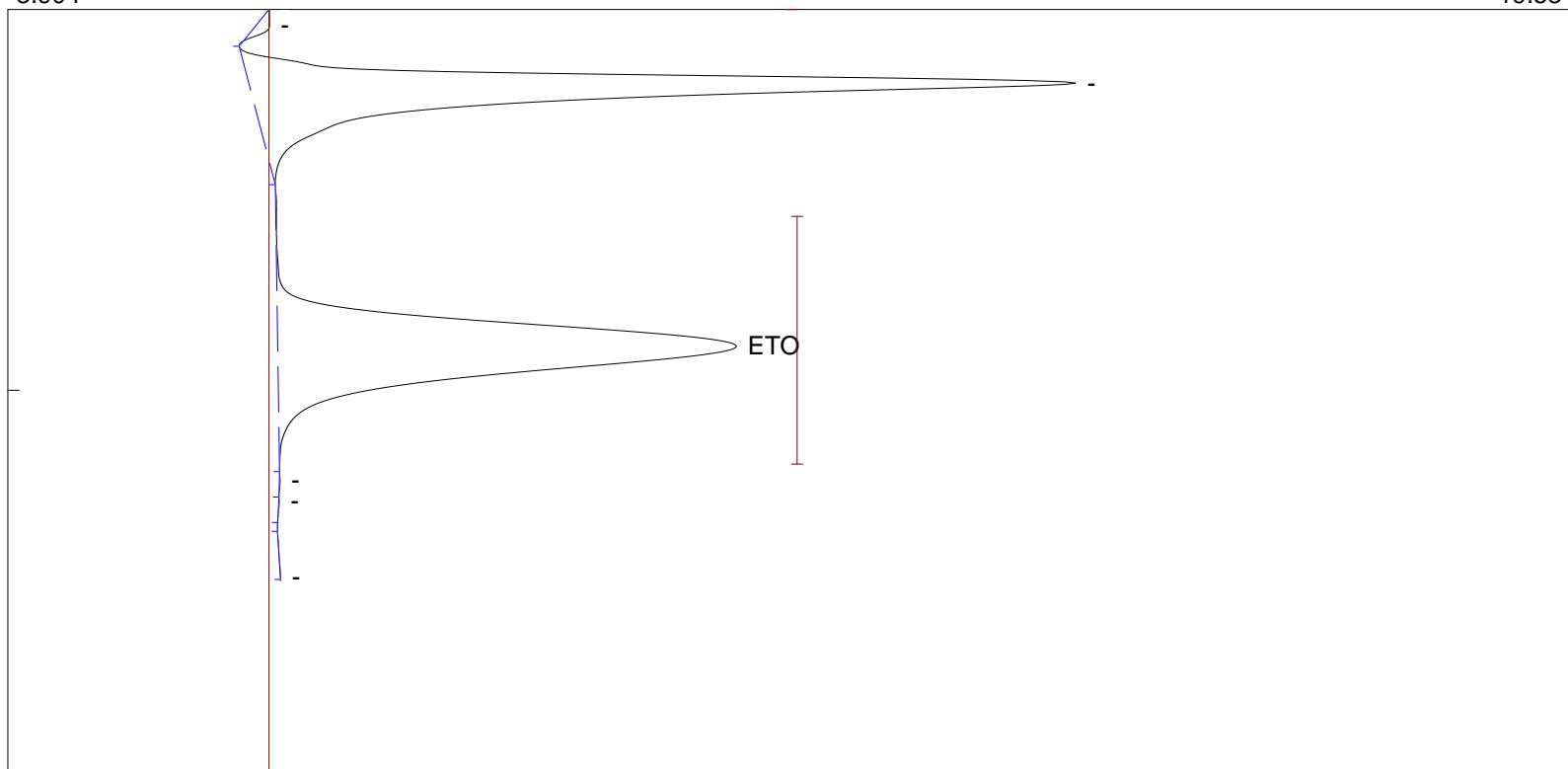
Sample: Sample

Operator: L Christopher Heilner

Comments: 10ppm Calibration gas

-3.904

19.531



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.883	59.9244
1			59.9244

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 08:26:55

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_875.()

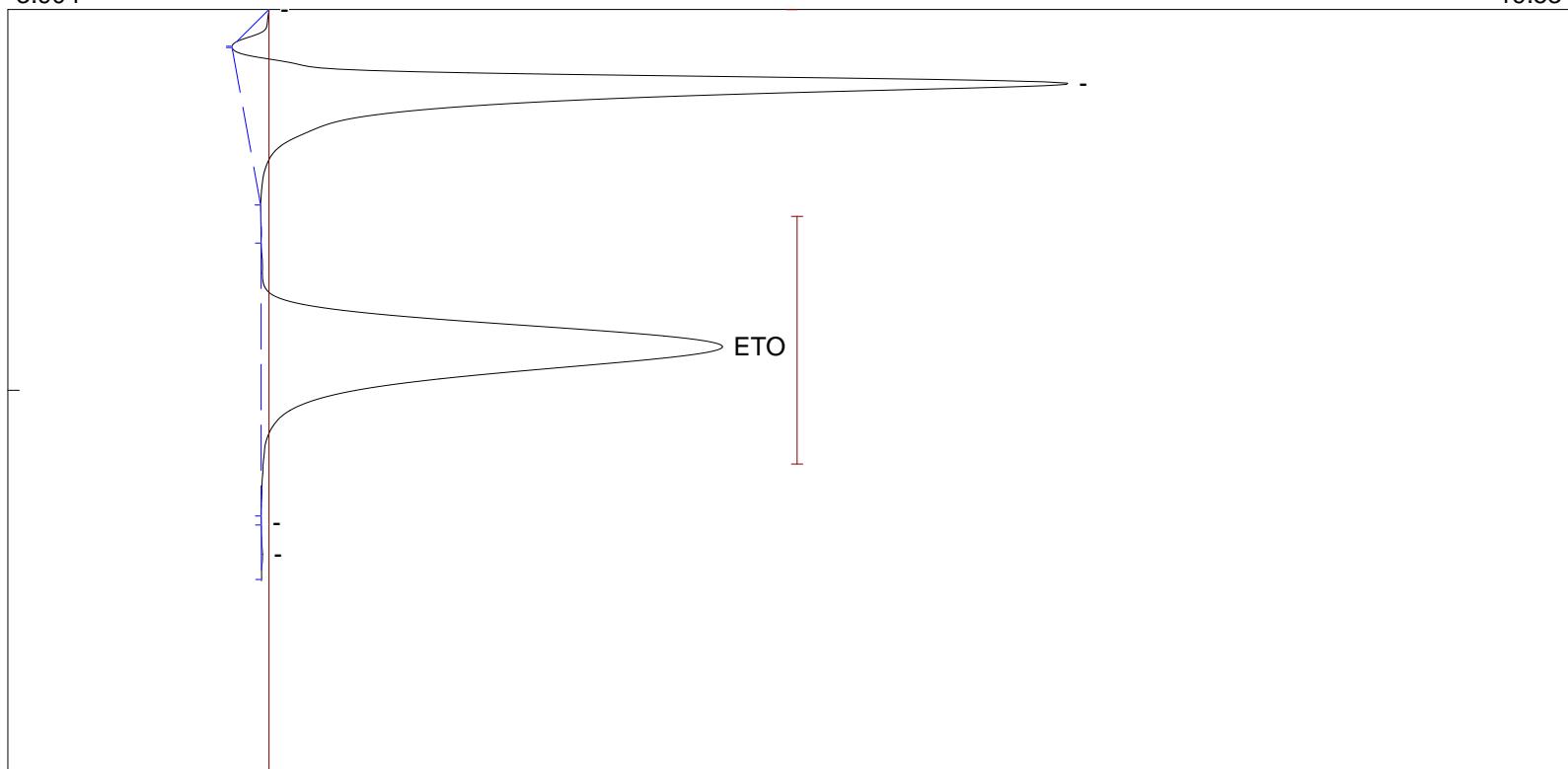
Sample: Sample

Operator: L Christopher Heilner

Comments: 10ppm Calibration gas

-3.904

19.531



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.886	60.4624
1			60.4624

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 08:45:50

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_881.()

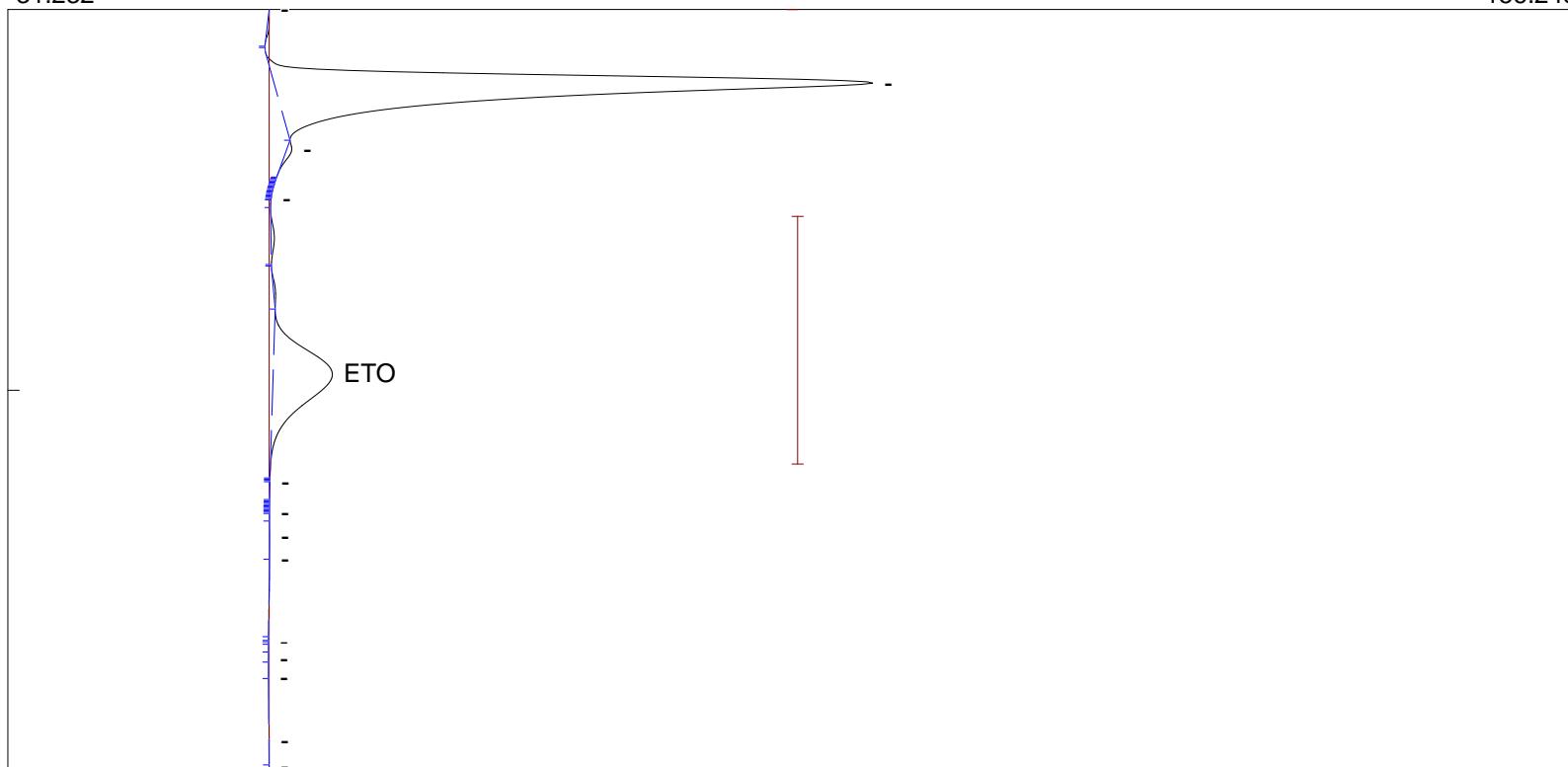
Sample: Sample

Operator: L Christopher Heilner

Comments: Scrubber Test 1

-31.232

156.248



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.956	68.5463
1			68.5463

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 08:52:54

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_883.()

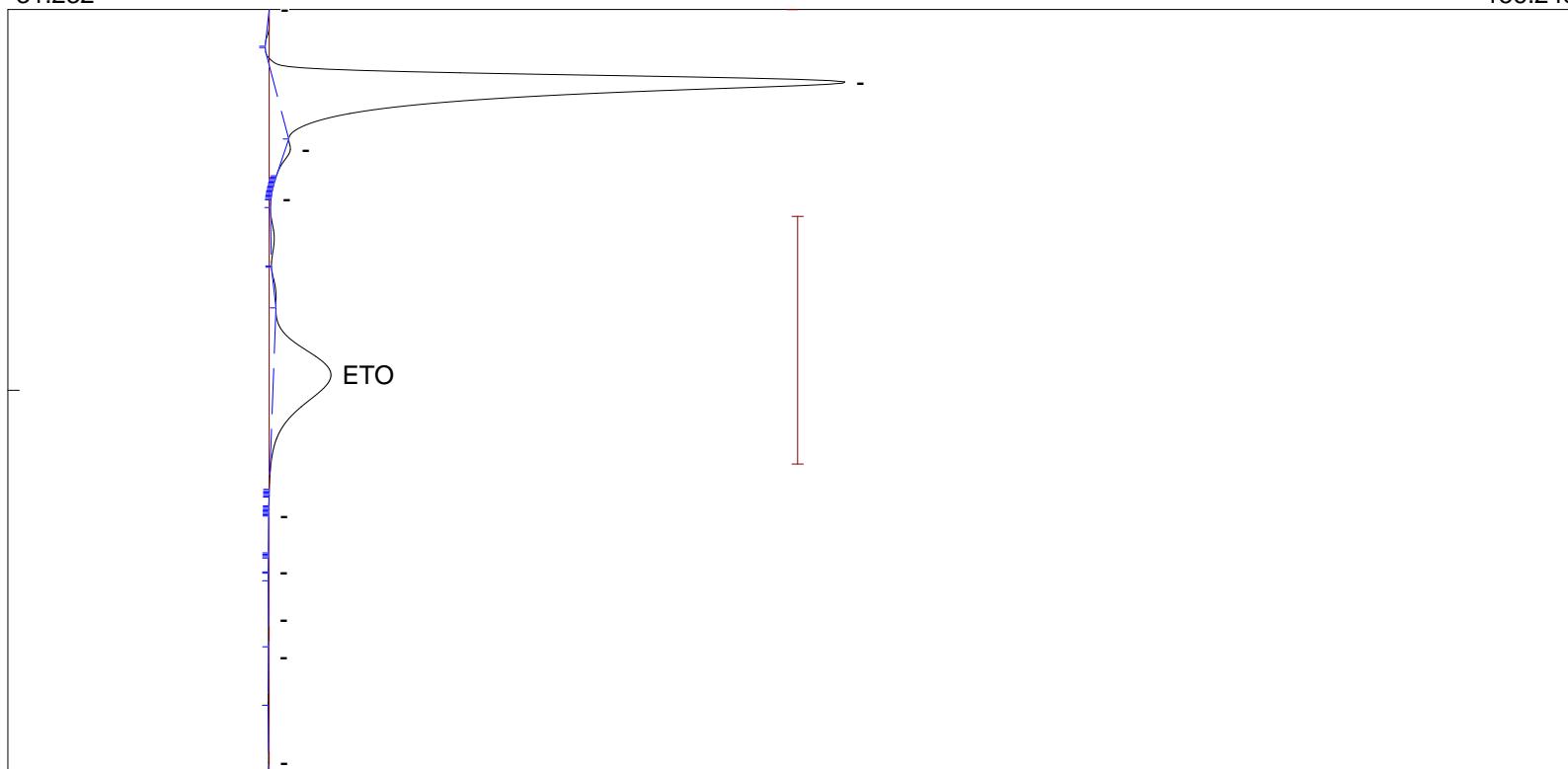
Sample: Sample

Operator: L Christopher Heilner

Comments: Scrubber Test 1

-31.232

156.248



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.960	68.1342
1			68.1342

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 08:56:42

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_884.()

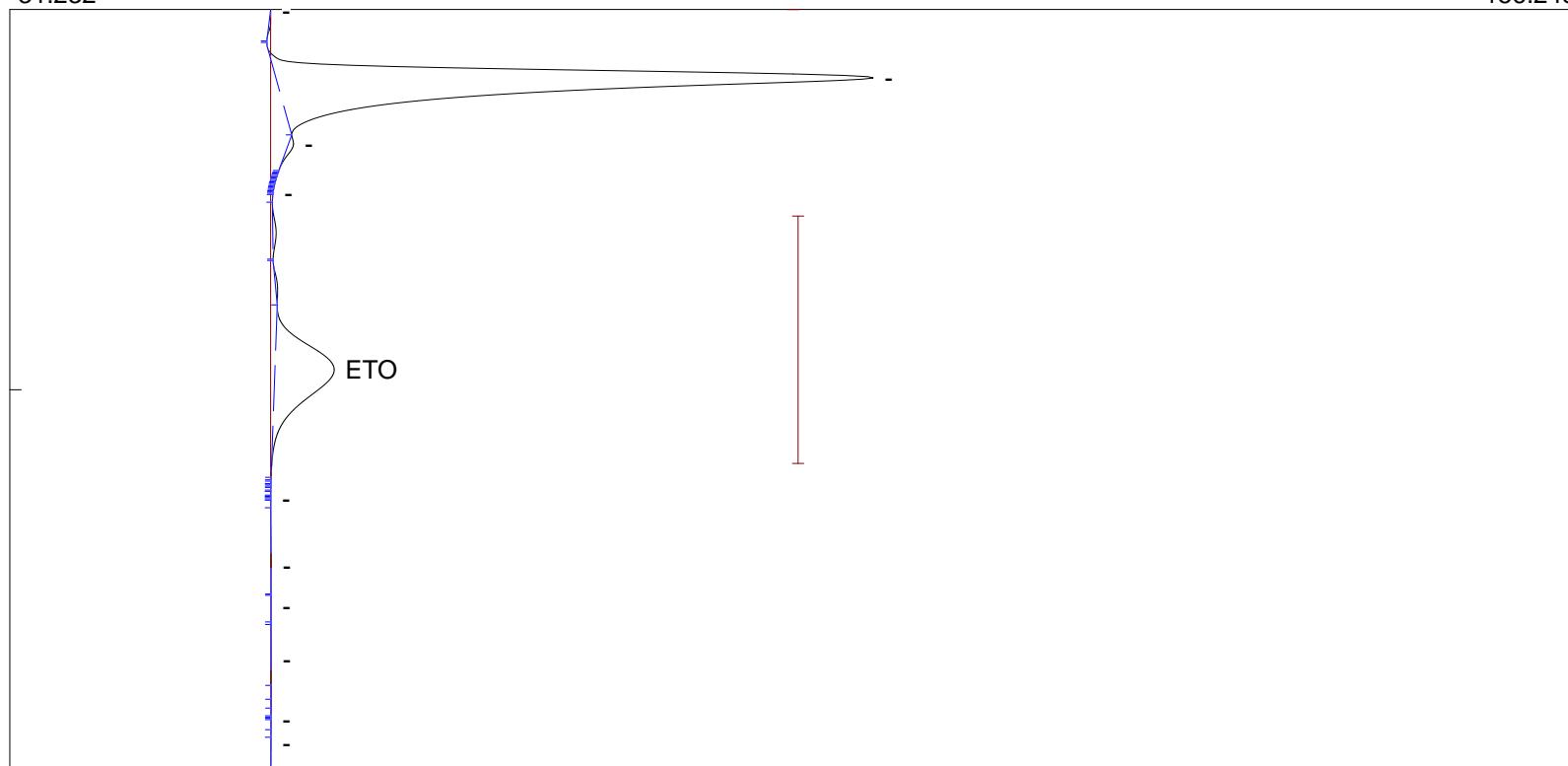
Sample: Sample

Operator: L Christopher Heilner

Comments: Scrubber Test 1

-31.232

156.248



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.946	68.9414
1			68.9414

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 16:24:36

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_887.()

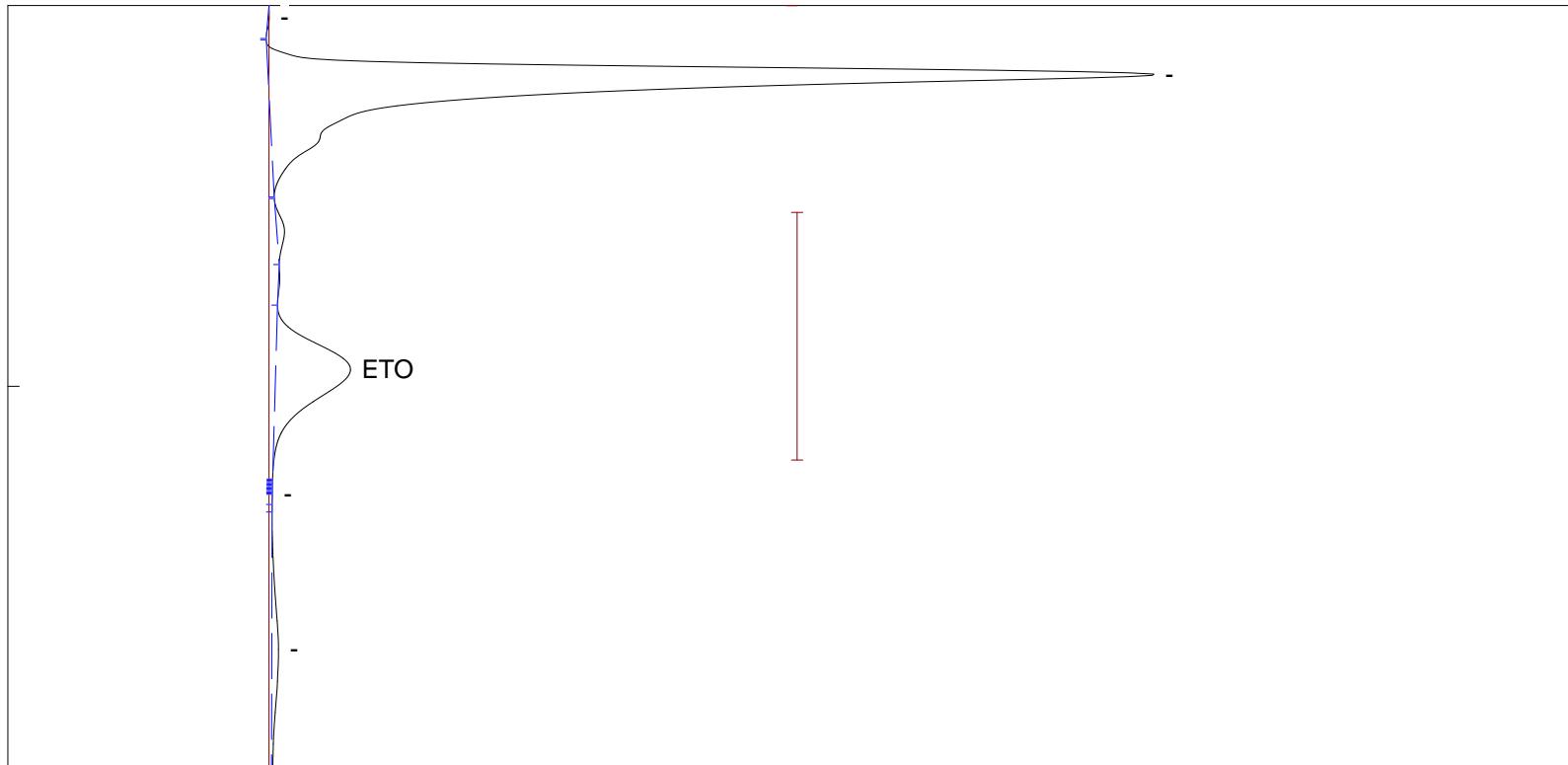
Sample: Sample

Operator: L Christopher Heilner

Comments: Scrubber Test 2

-31.232

156.248



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.956	89.7374
1			89.7374

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 16:28:02

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_888.()

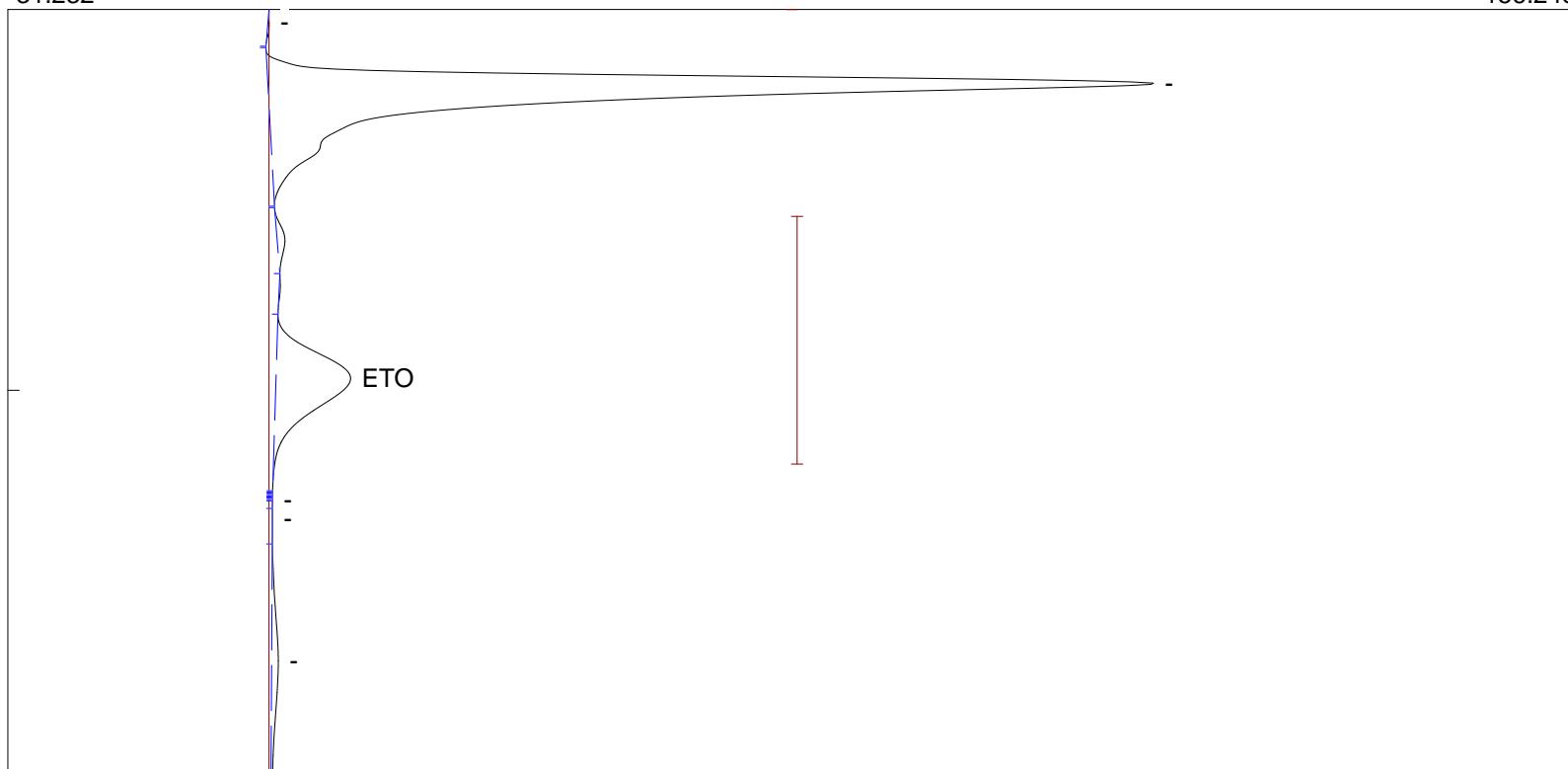
Sample: Sample

Operator: L Christopher Heilner

Comments: Scrubber Test 2

-31.232

156.248



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.970	89.5103
1			89.5103

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 16:31:32

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_889.()

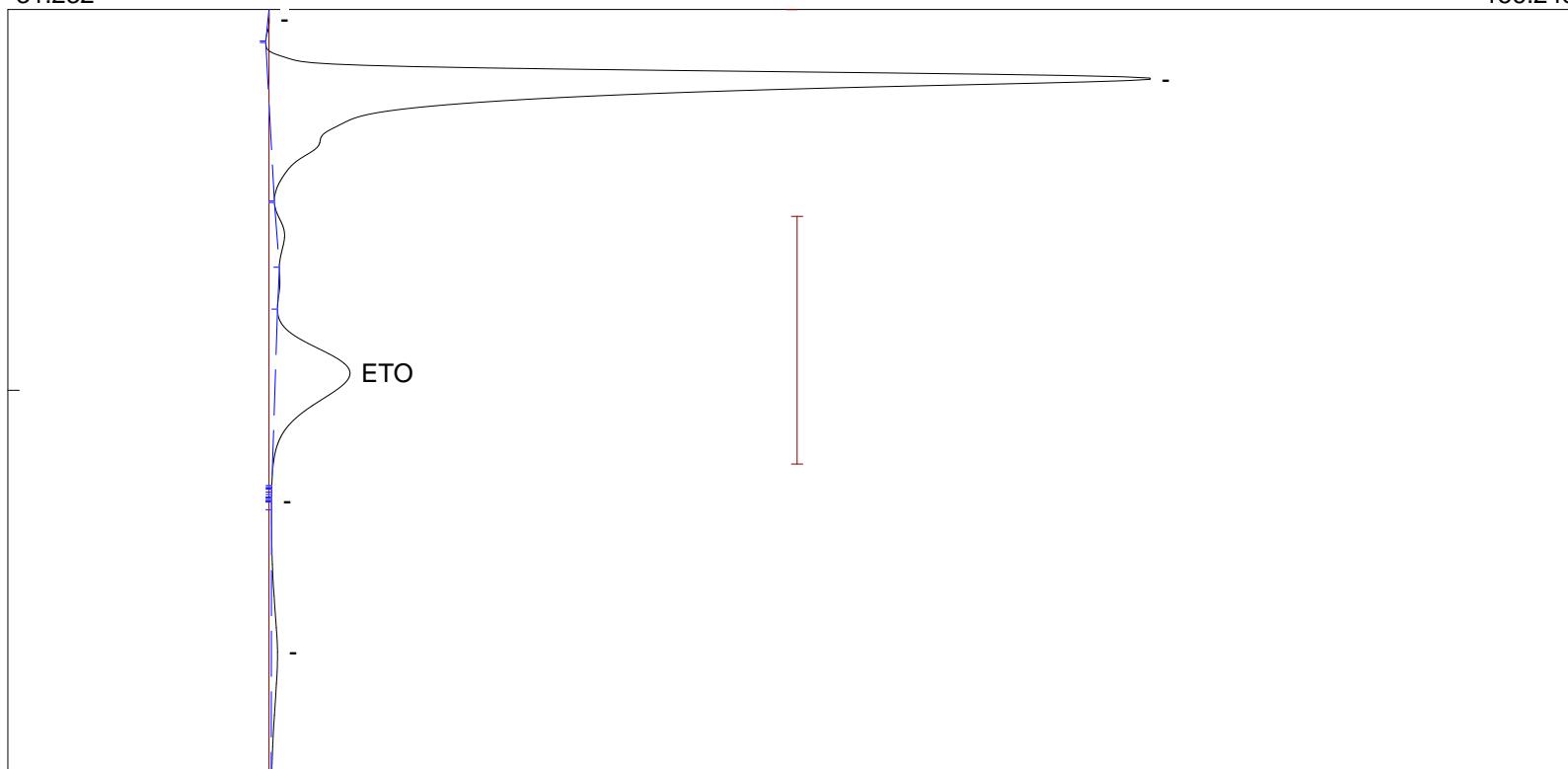
Sample: Sample

Operator: L Christopher Heilner

Comments: Scrubber Test 2

-31.232

156.248



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.956	89.4434
1			89.4434

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 16:43:10

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

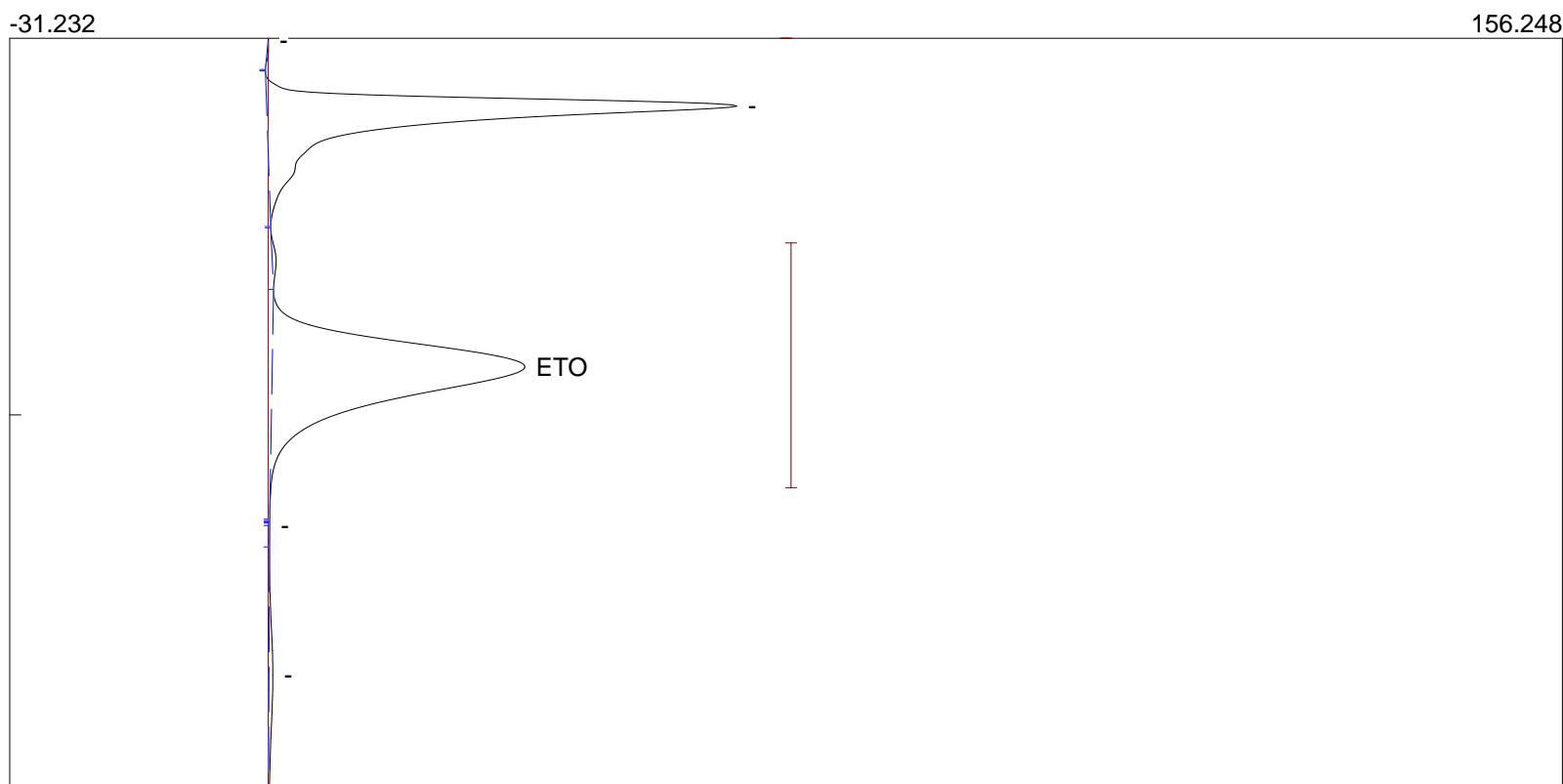
Data file: Customed2019_Q4_891.()

Sample: Sample

Operator: L Christopher Heilner

Comments: Scrubber Test 2

Recovery Study Initial



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	306.0619
1			306.0619

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 16:54:17

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

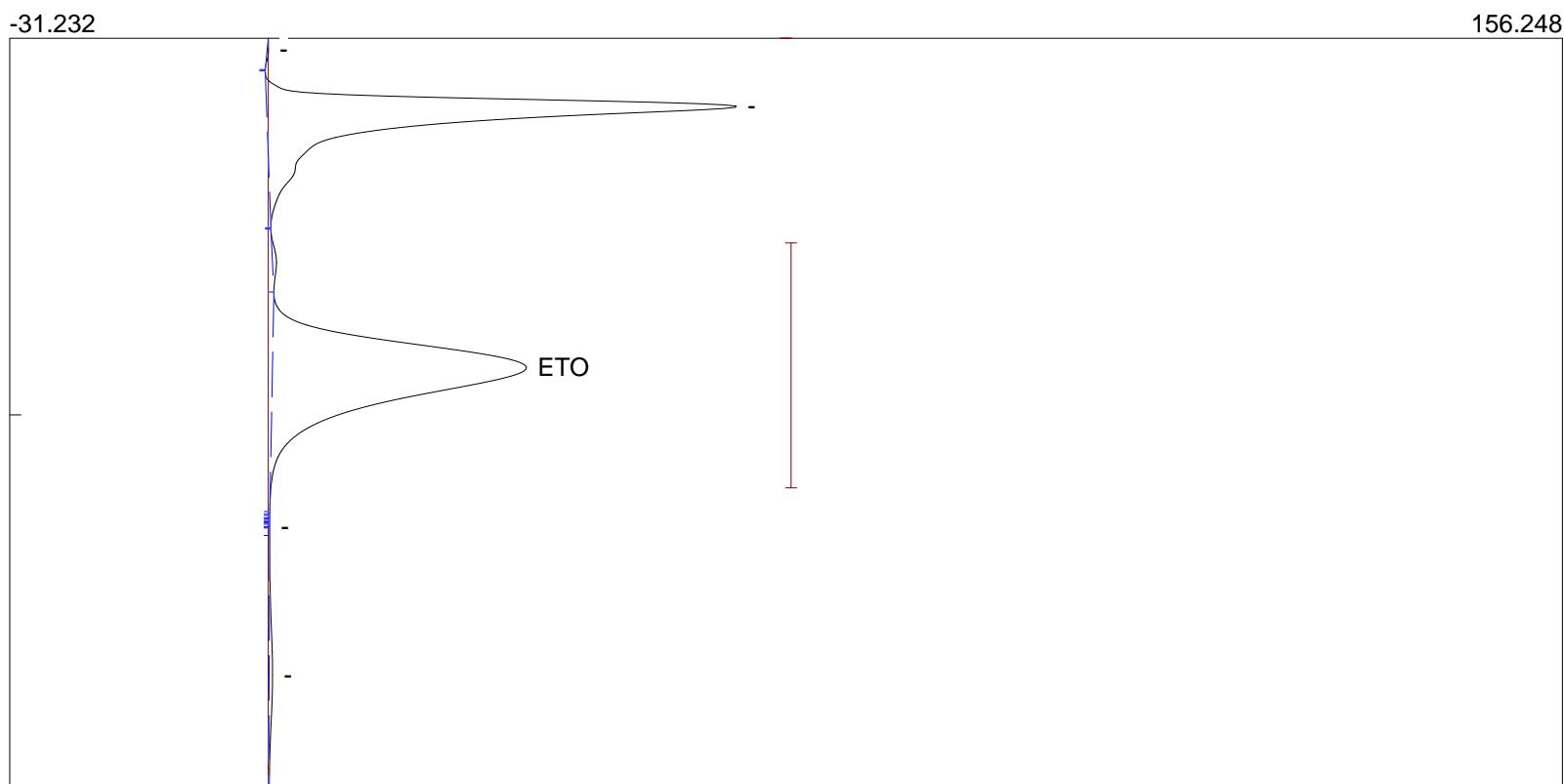
Data file: Customed2019_Q4_894.()

Sample: Sample

Operator: L Christopher Heilner

Comments: Scrubber Test 2

Recovery Study Initial



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	306.8794
1			306.8794

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 17:01:15

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

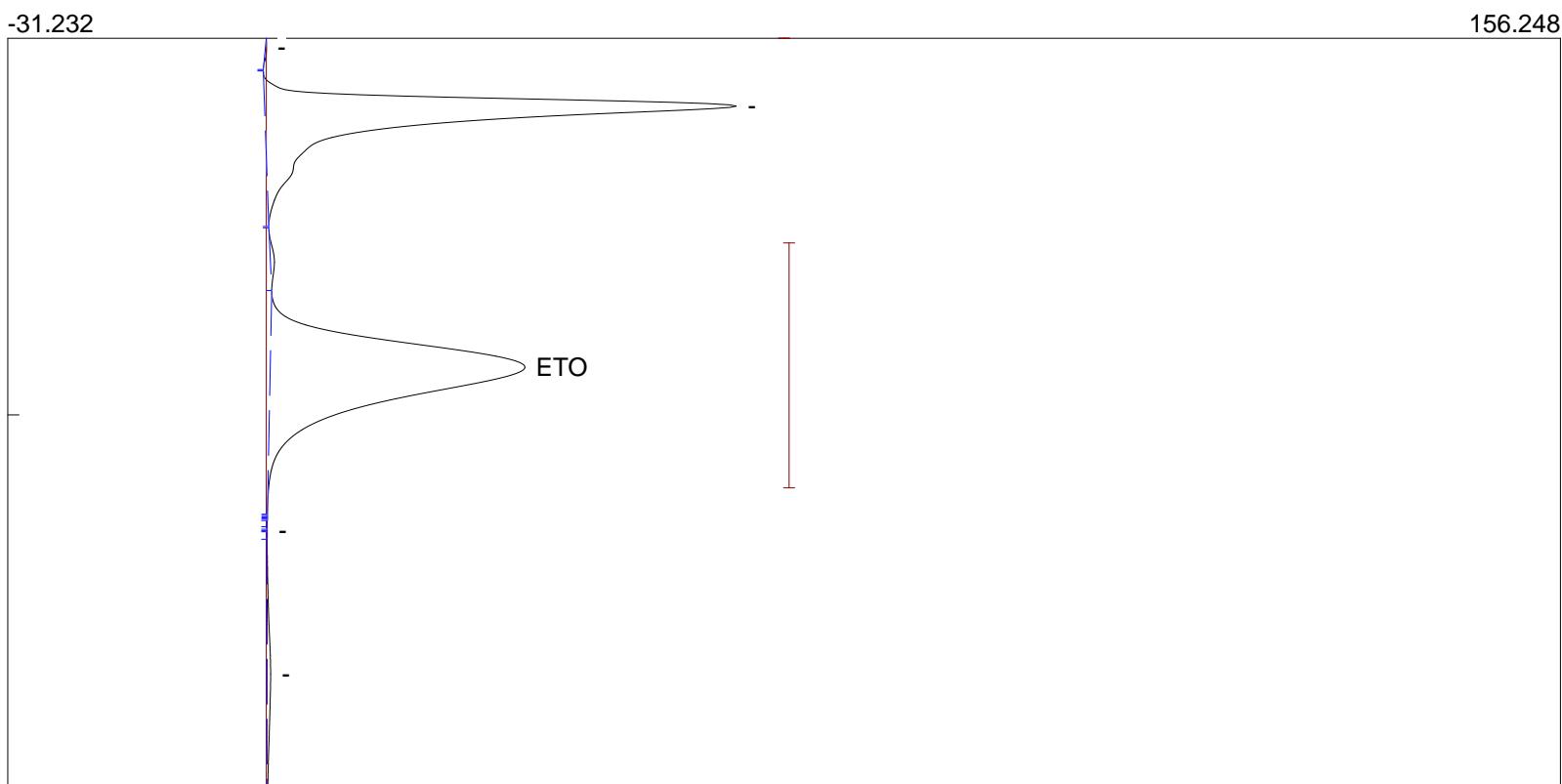
Data file: Customed2019_Q4_896.()

Sample: Sample

Operator: L Christopher Heilner

Comments: Scrubber Test 2

Recovery Study Initial



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	308.1706
1			308.1706

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 17:22:01

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_905.()

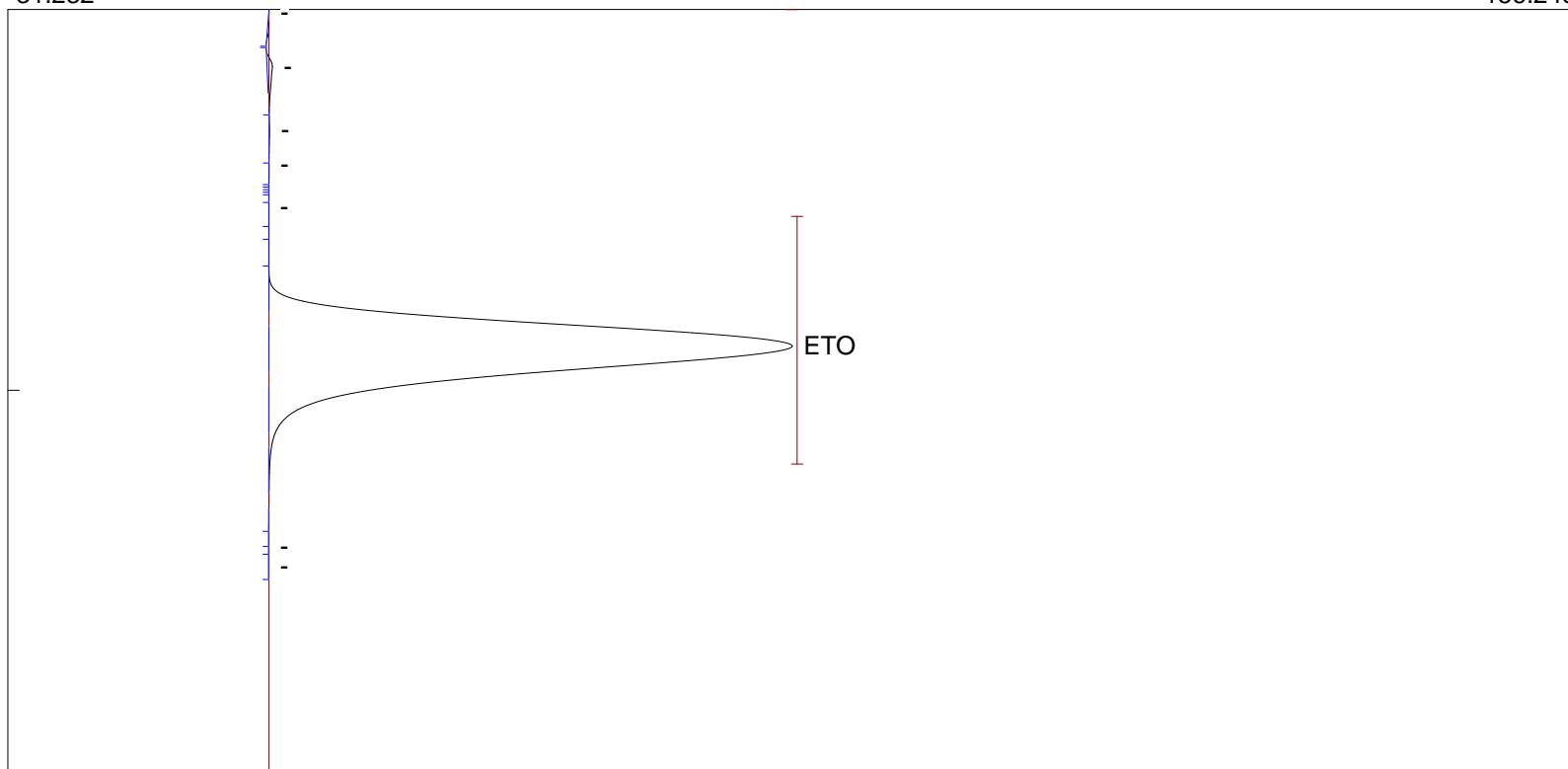
Sample: Sample

Operator: L Christopher Heilner

Comments: 100ppm Cal Gas

-31.232

156.248



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.883	542.2717
1			542.2717

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 17:23:43

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_906.()

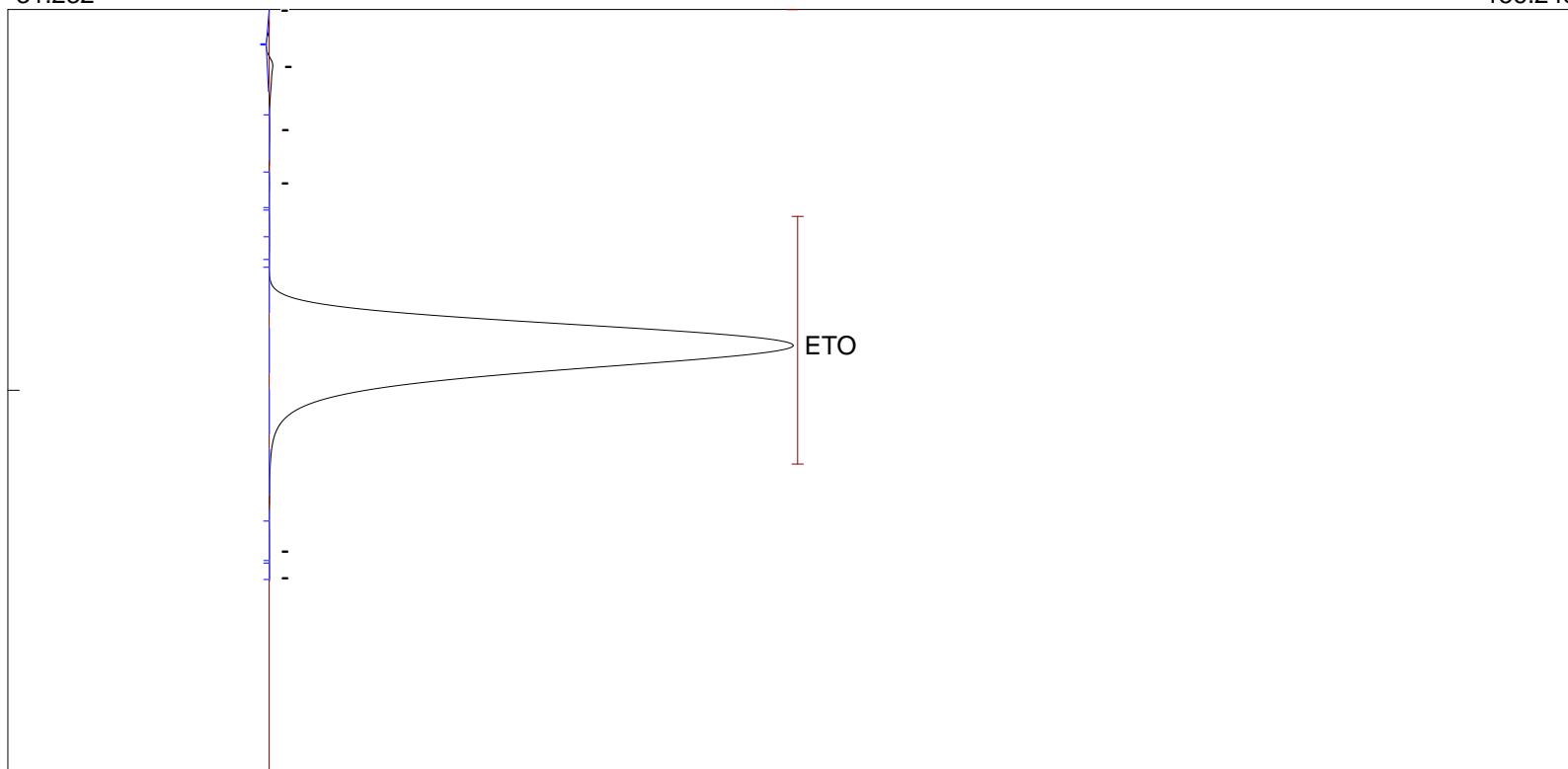
Sample: Sample

Operator: L Christopher Heilner

Comments: 100ppm Cal Gas

-31.232

156.248



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.883	542.0292
1			542.0292

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 17:25:20

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_907.()

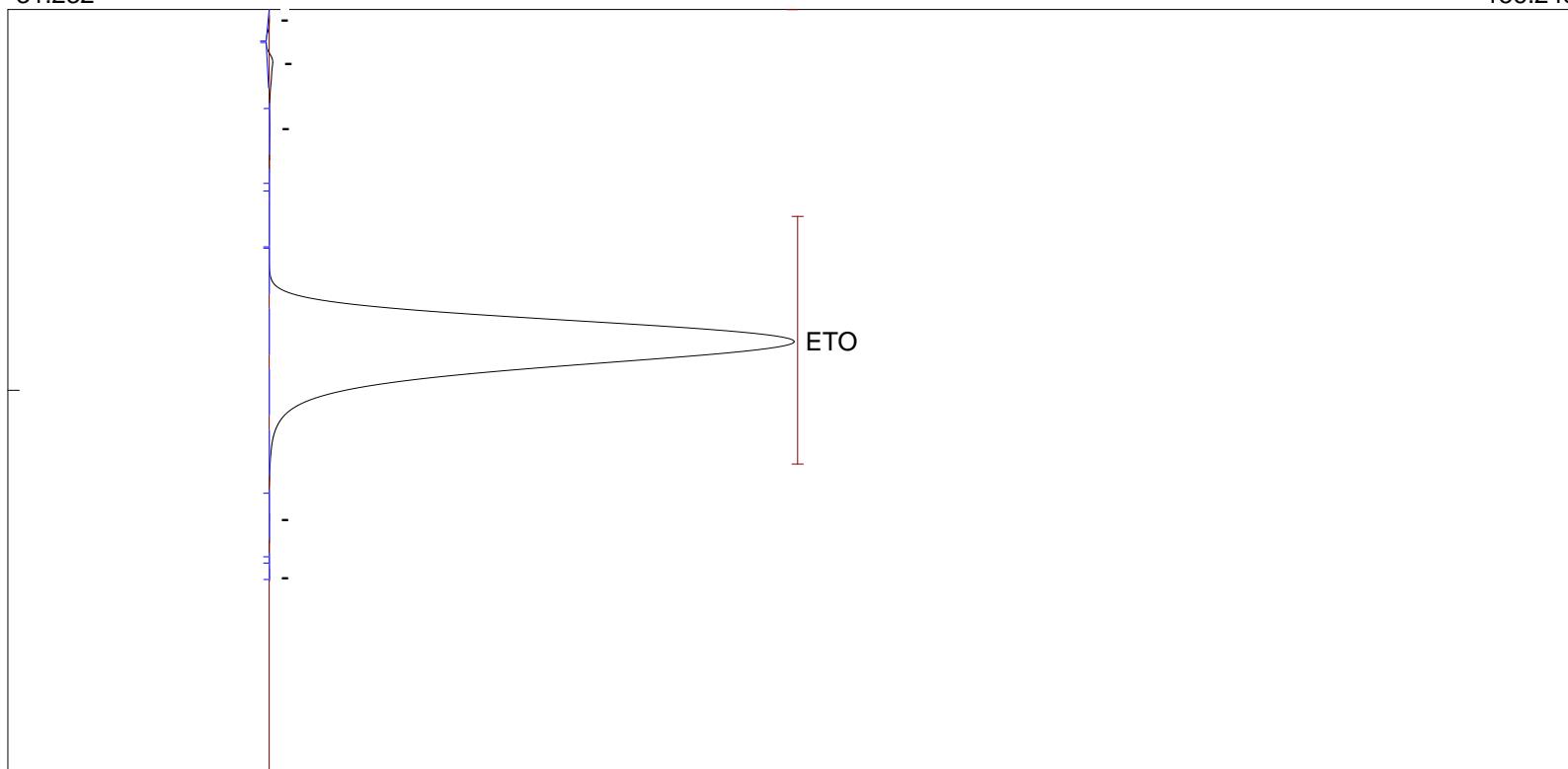
Sample: Sample

Operator: L Christopher Heilner

Comments: 100ppm Cal Gas

-31.232

156.248



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	542.7906
1			542.7906

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 17:39:30

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_914.()

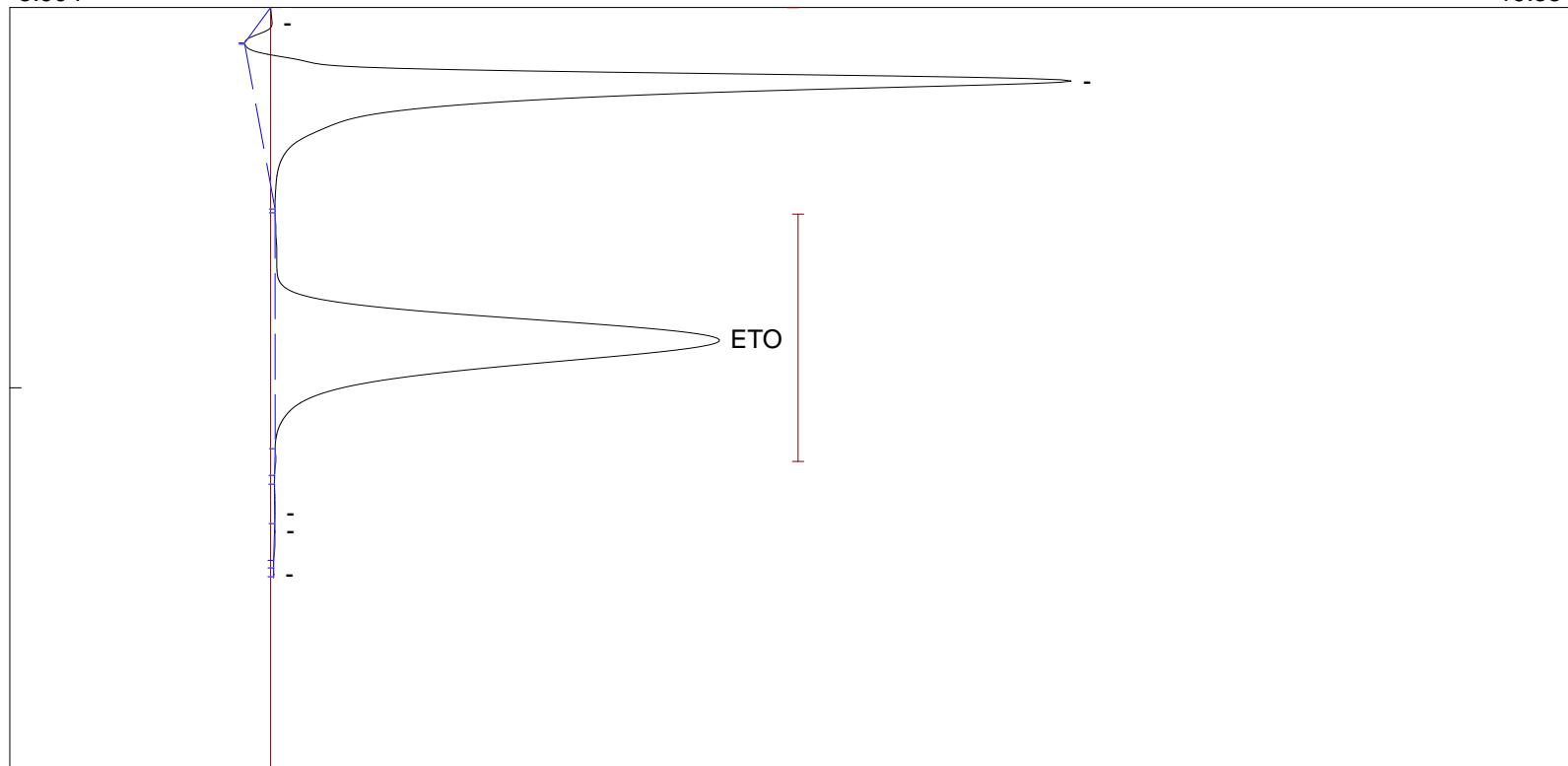
Sample: Sample

Operator: L Christopher Heilner

Comments: 10ppm Cal Gas

-3.904

19.531



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	57.1820
1			57.1820

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 17:41:22

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_915.()

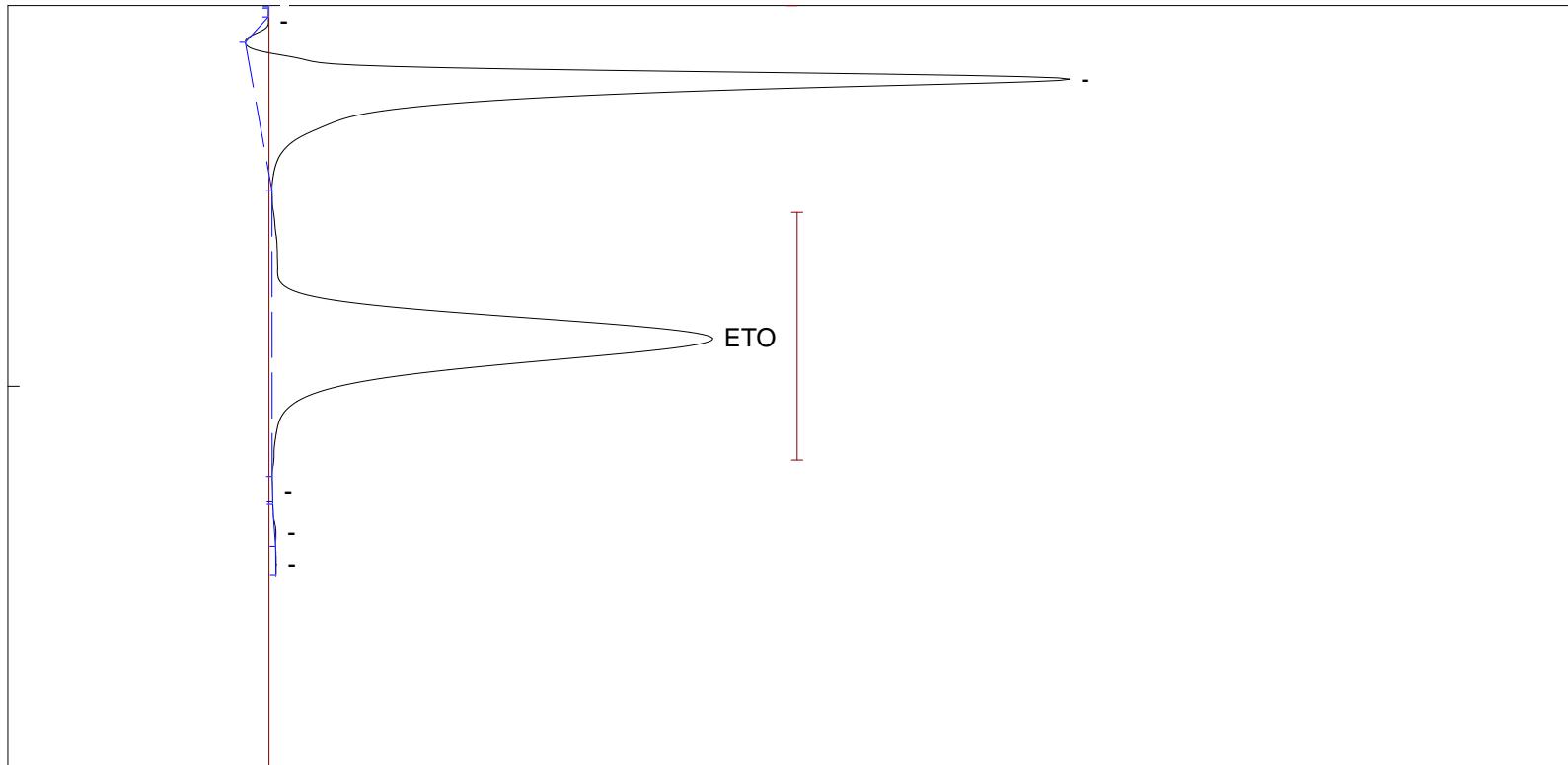
Sample: Sample

Operator: L Christopher Heilner

Comments: 10ppm Cal Gas

-3.904

19.531



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	57.6427
1			57.6427

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 17:43:04

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_916.()

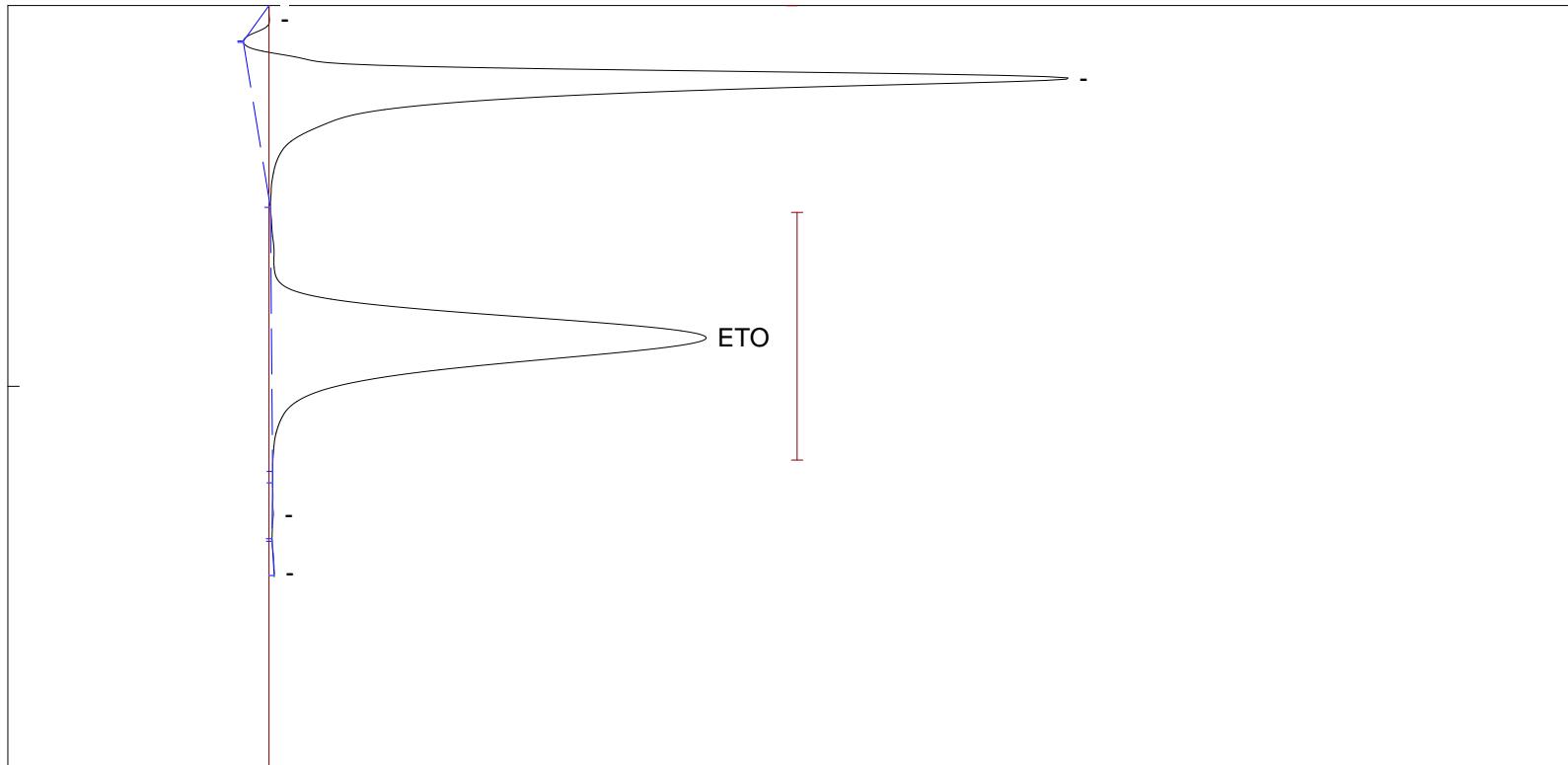
Sample: Sample

Operator: L Christopher Heilner

Comments: 10ppm Cal Gas

-3.904

19.531



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	56.6848
1			56.6848

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 17:52:34

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

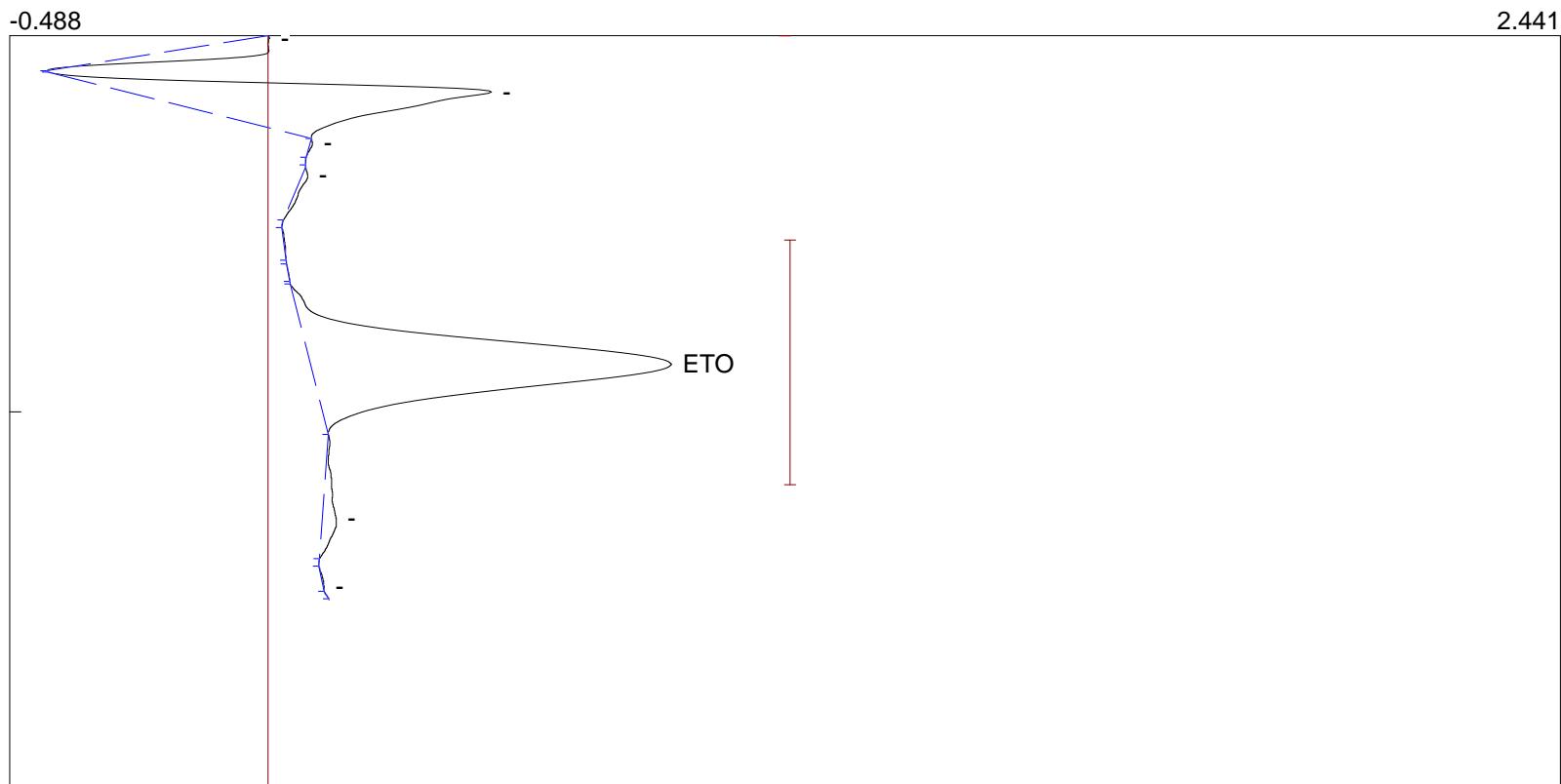
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_919.()

Sample: Sample

Operator: L Christopher Heilner

Comments: 1ppm Cal Gas



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	5.8788
1			5.8788

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 17:54:06

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

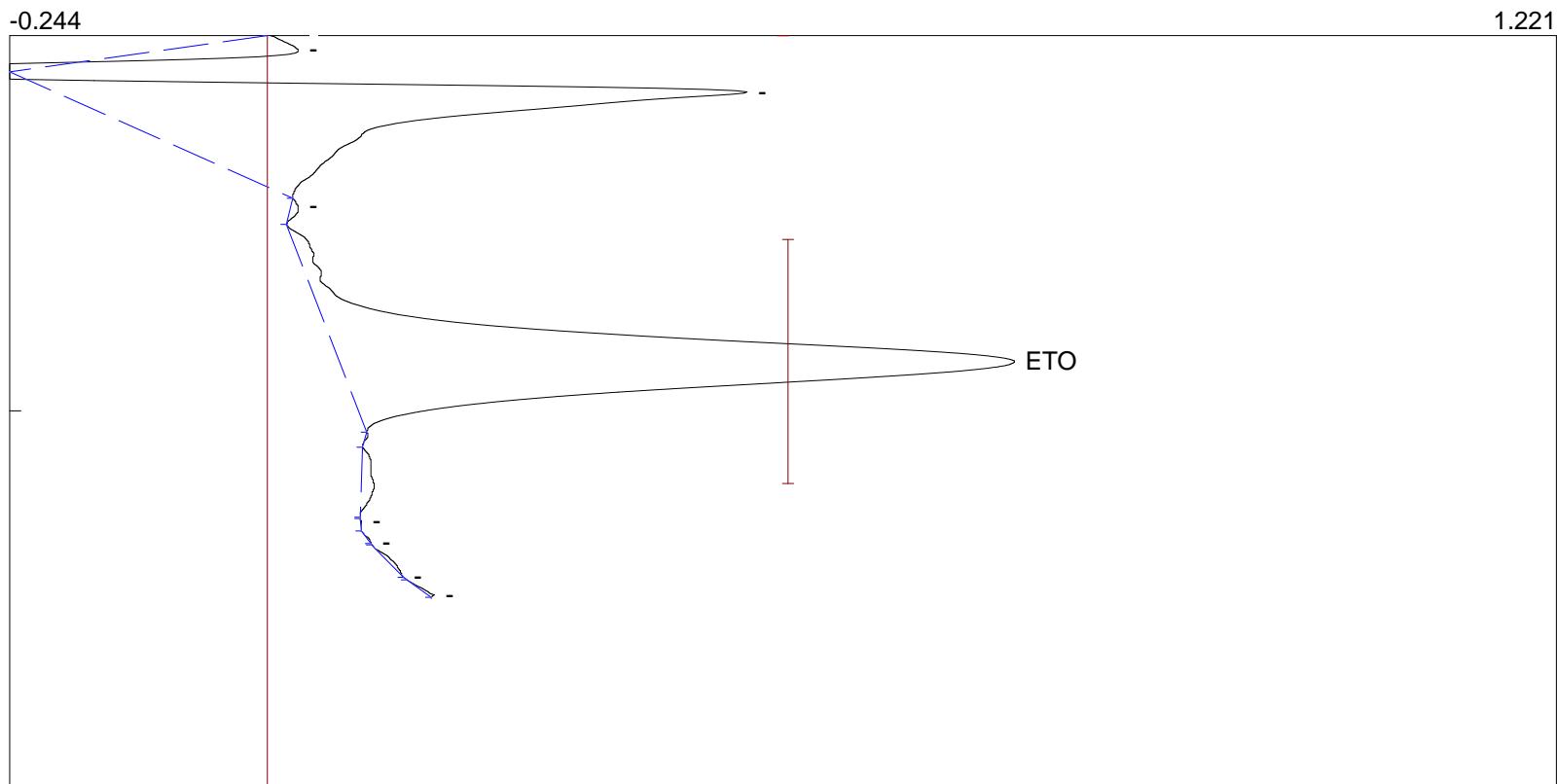
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_920.()

Sample: Sample

Operator: L Christopher Heilner

Comments: 1ppm Cal Gas



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.866	5.7524
1			5.7524

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 17:55:41

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

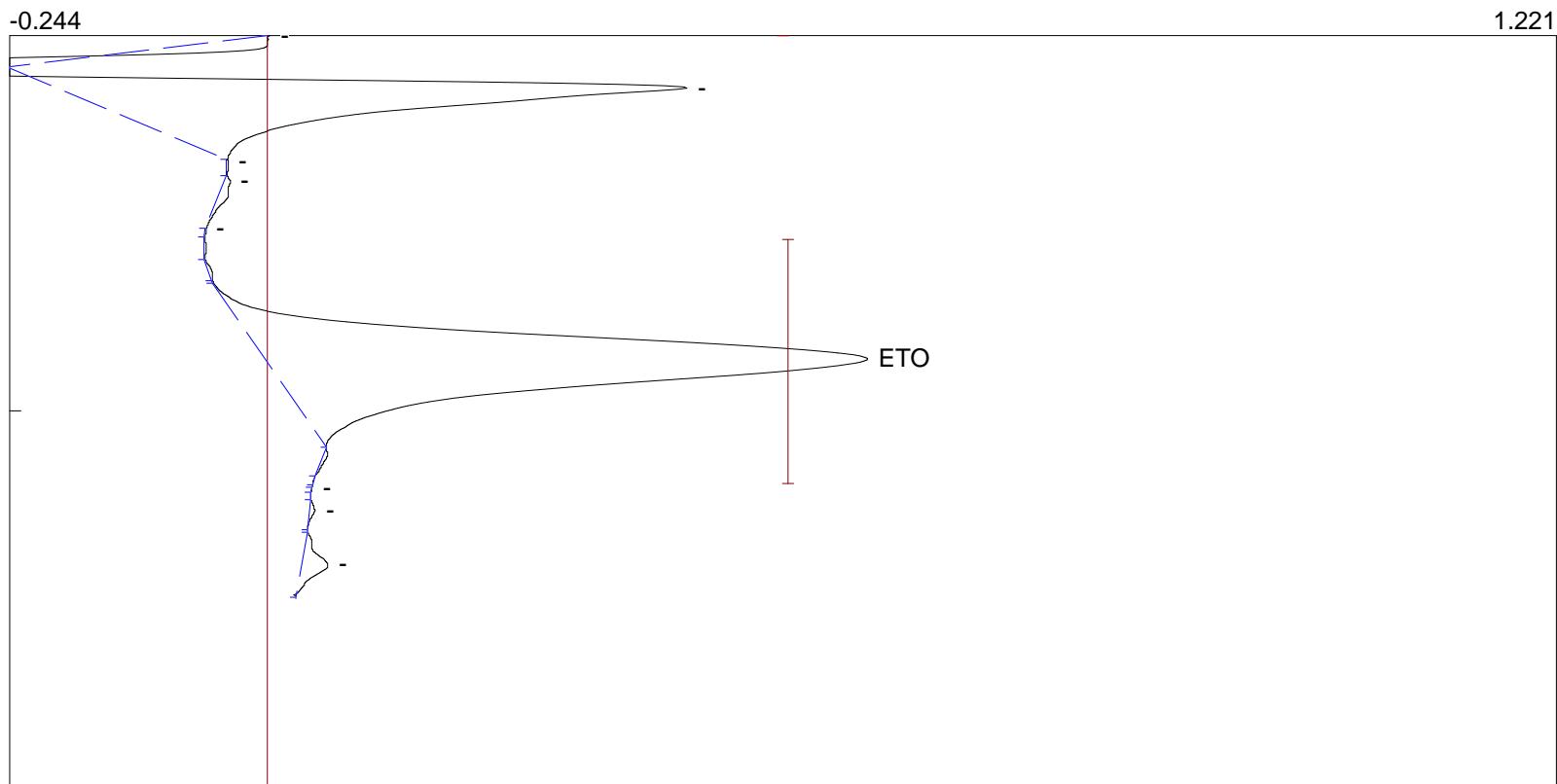
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_921.()

Sample: Sample

Operator: L Christopher Heilner

Comments: 1ppm Cal Gas



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.860	5.8756
1			5.8756

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 18:11:01

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_928.()

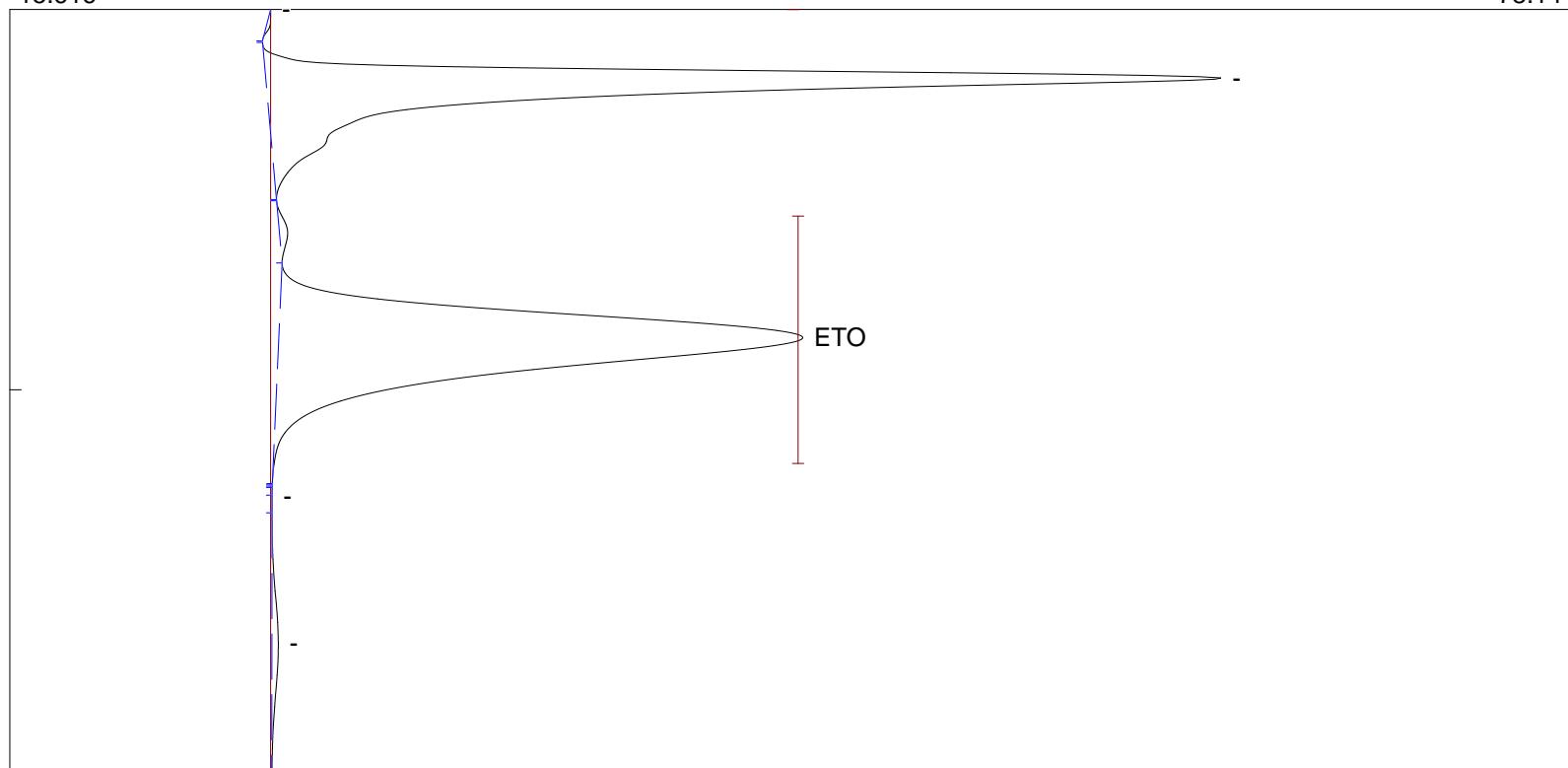
Sample: Sample

Operator: L Christopher Heilner

Comments: Recovery Study Final

-15.616

78.144



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.863	309.7882
1			309.7882

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 18:14:43

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_929.()

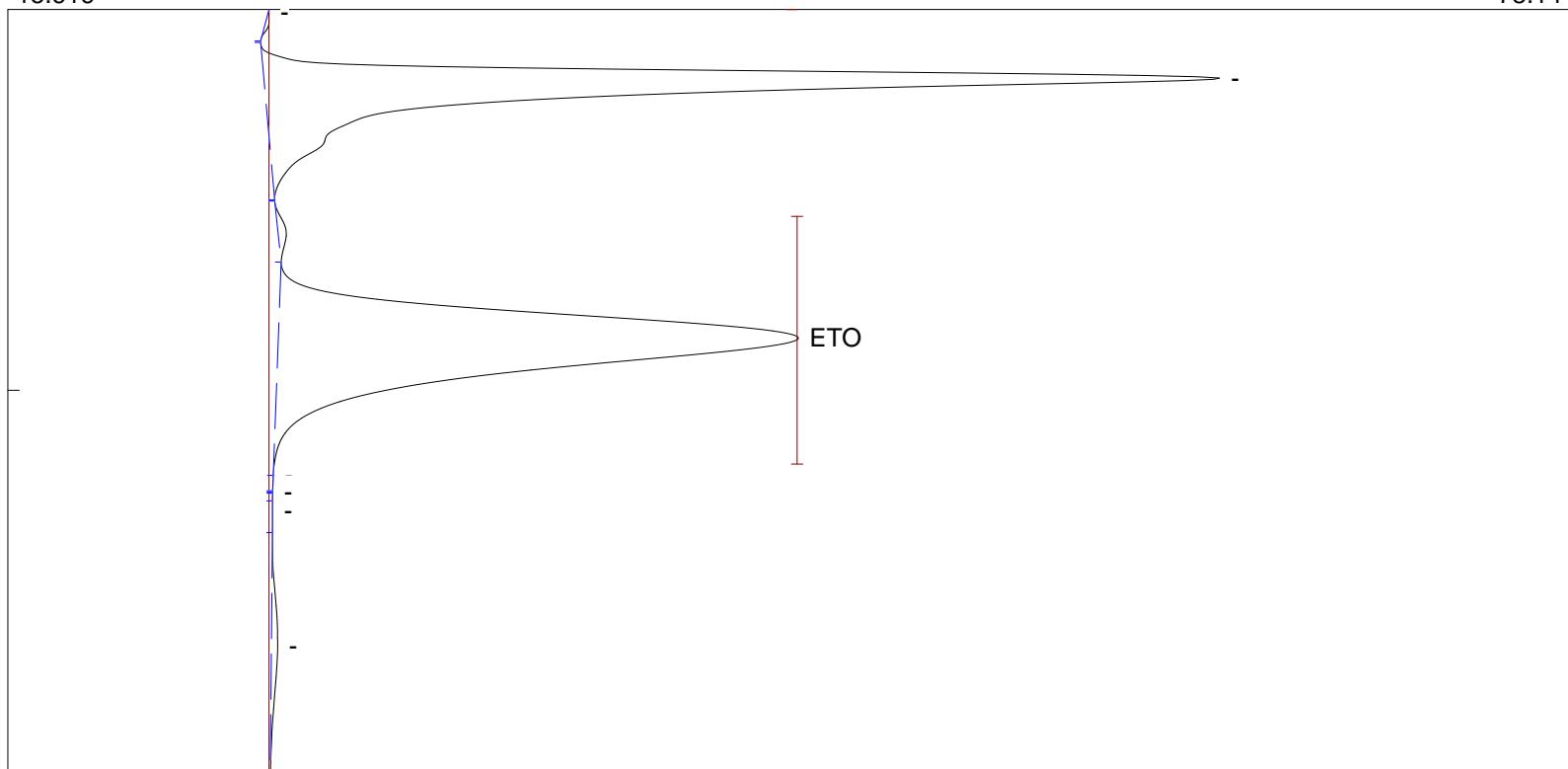
Sample: Sample

Operator: L Christopher Heilner

Comments: Recovery Study Final

-15.616

78.144



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.863	307.3648
1			307.3648

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 18:18:26

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_930.()

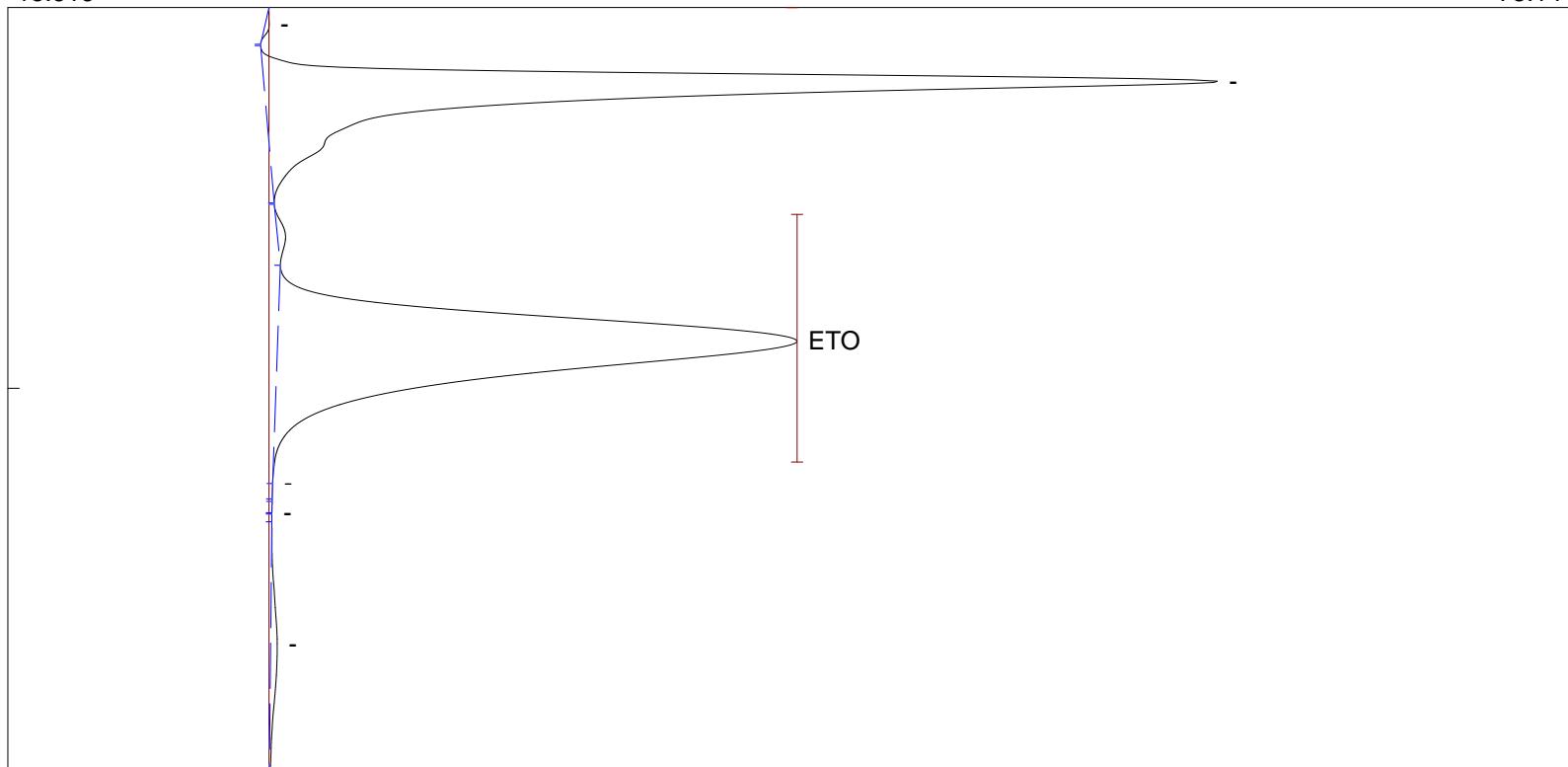
Sample: Sample

Operator: L Christopher Heilner

Comments: Recovery Study Final

-15.616

78.144



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.876	307.0918
1			307.0918

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 18:39:43

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_936.()

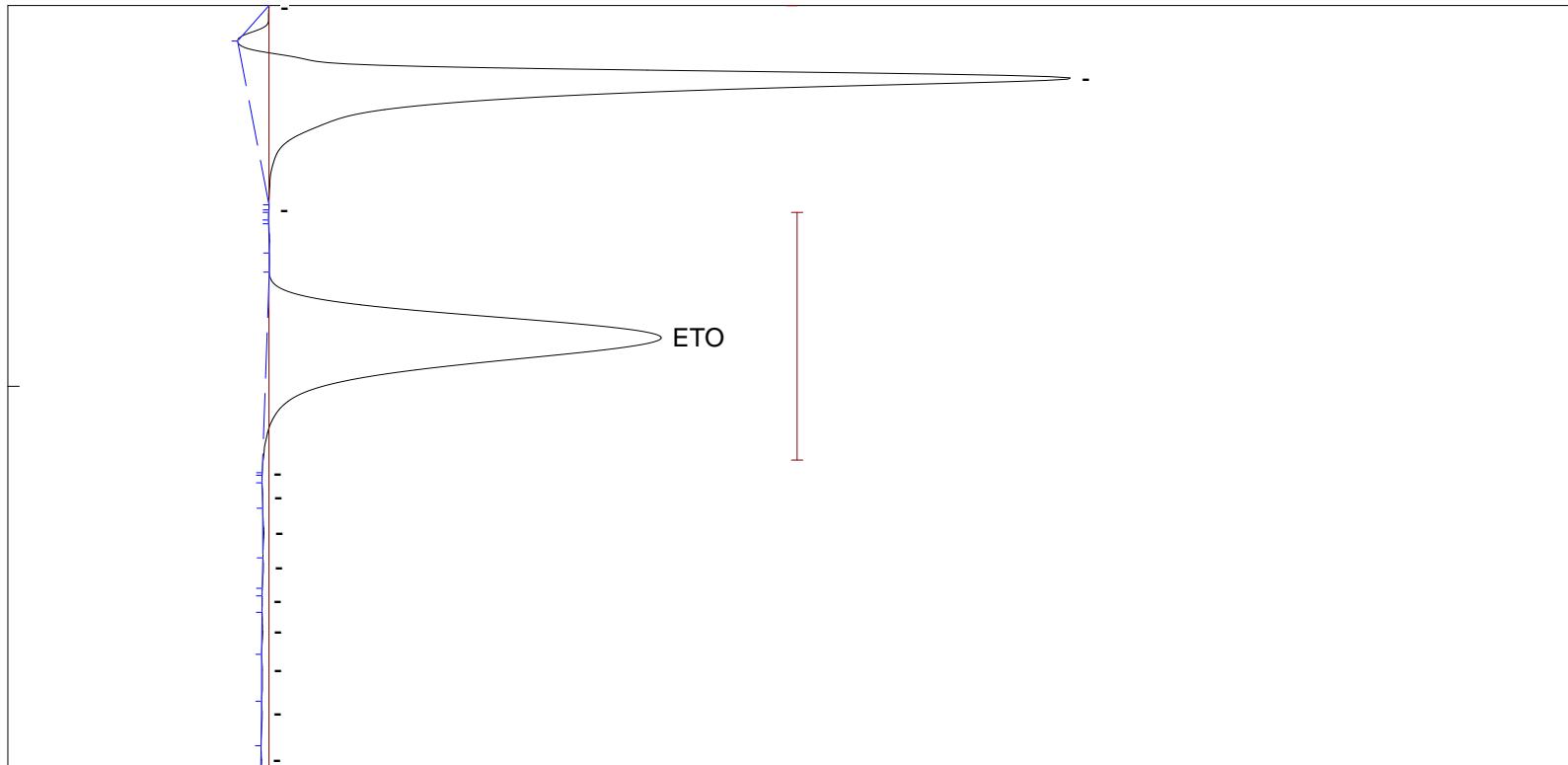
Sample: Sample

Operator: L Christopher Heilner

Comments: Direct Interface Recovery Study

-3.904

19.536



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	56.7228
1			56.7228

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 18:42:57

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_937.()

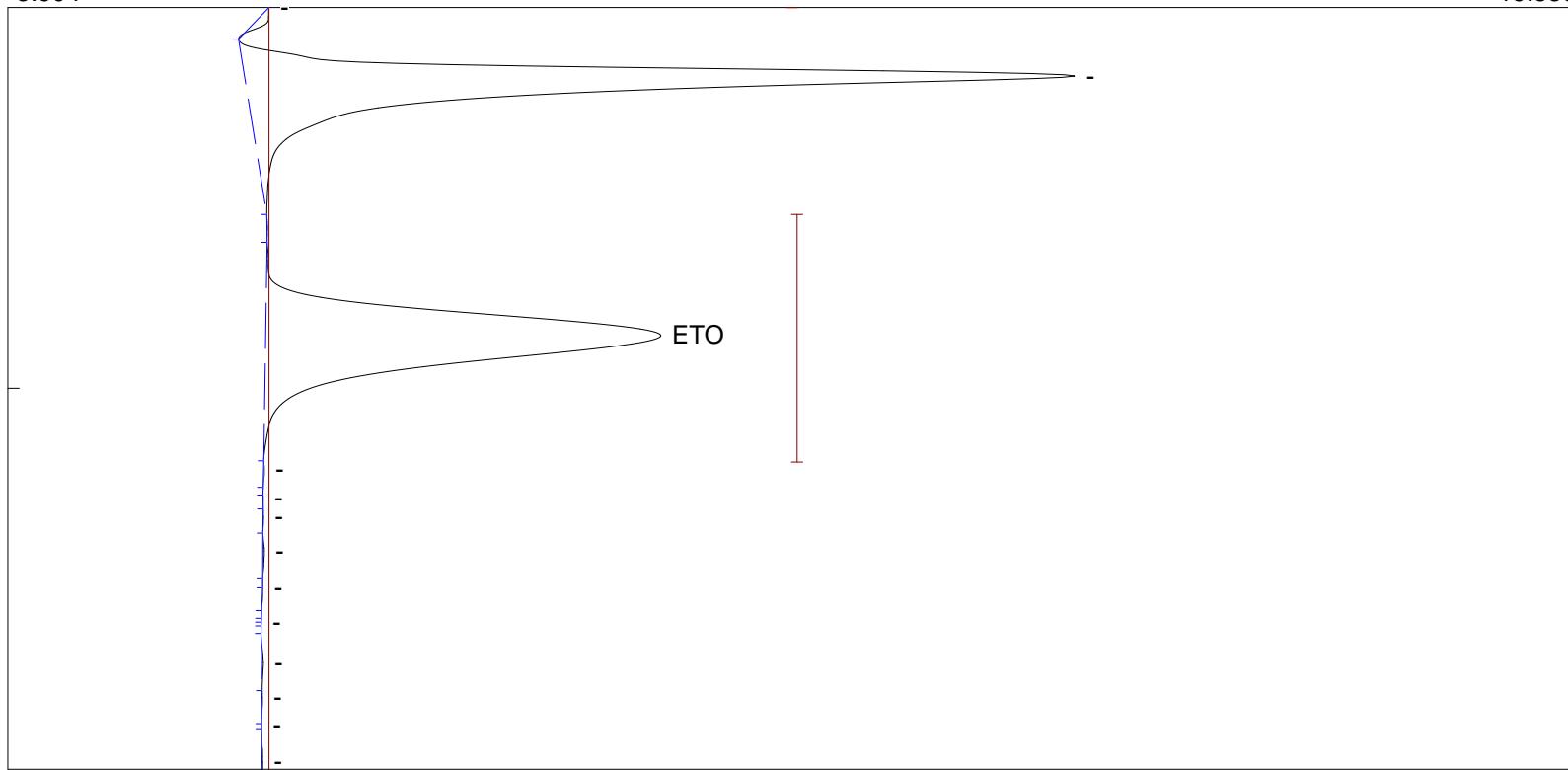
Sample: Sample

Operator: L Christopher Heilner

Comments: Direct Interface Recovery Study

-3.904

19.536



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.860	57.9918
1			57.9918

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 12/31/2019 18:46:00

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_938.()

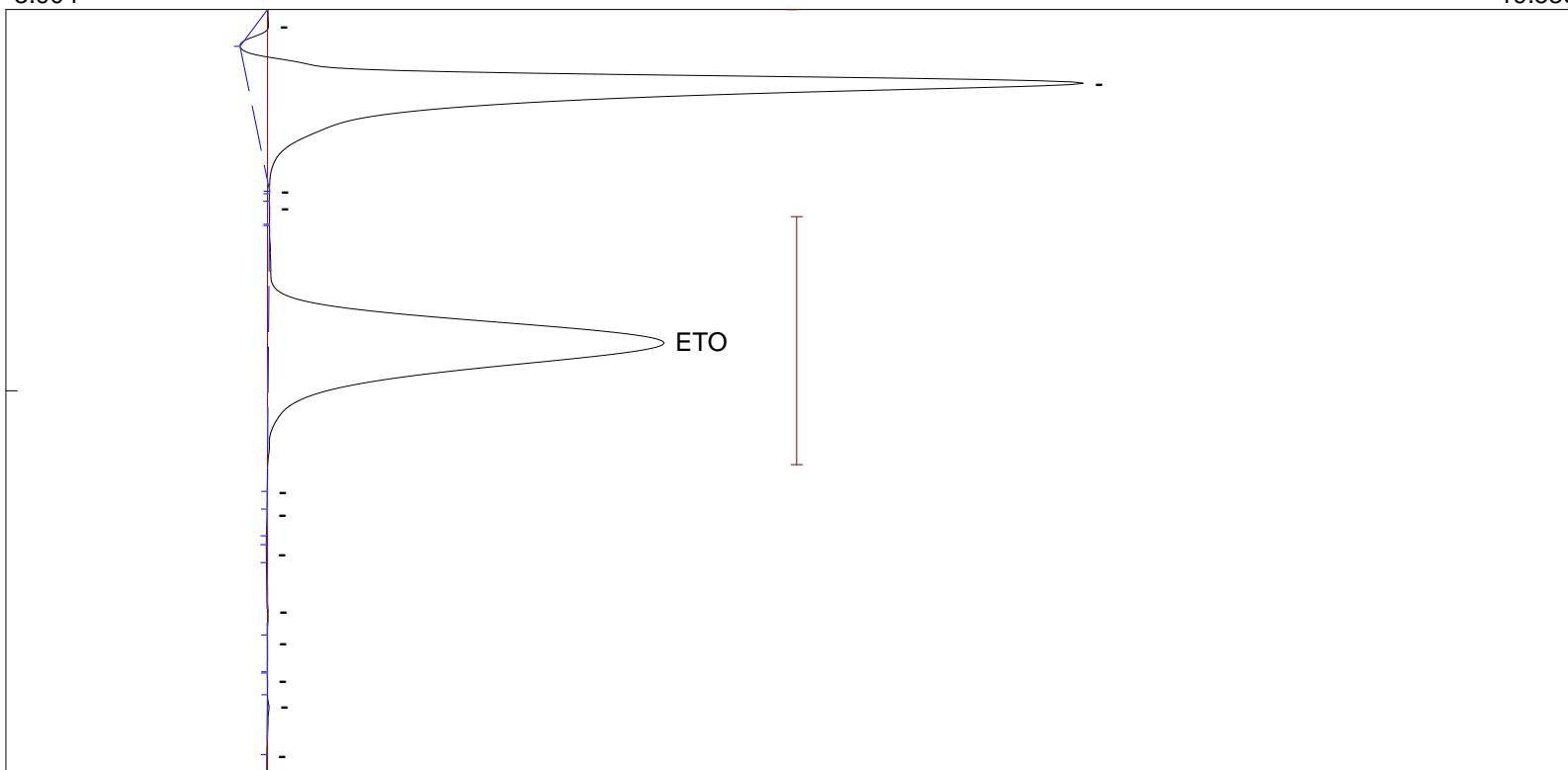
Sample: Sample

Operator: L Christopher Heilner

Comments: Direct Interface Recovery Study

-3.904

19.536



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	57.6547
1			57.6547

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 21:03:34

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

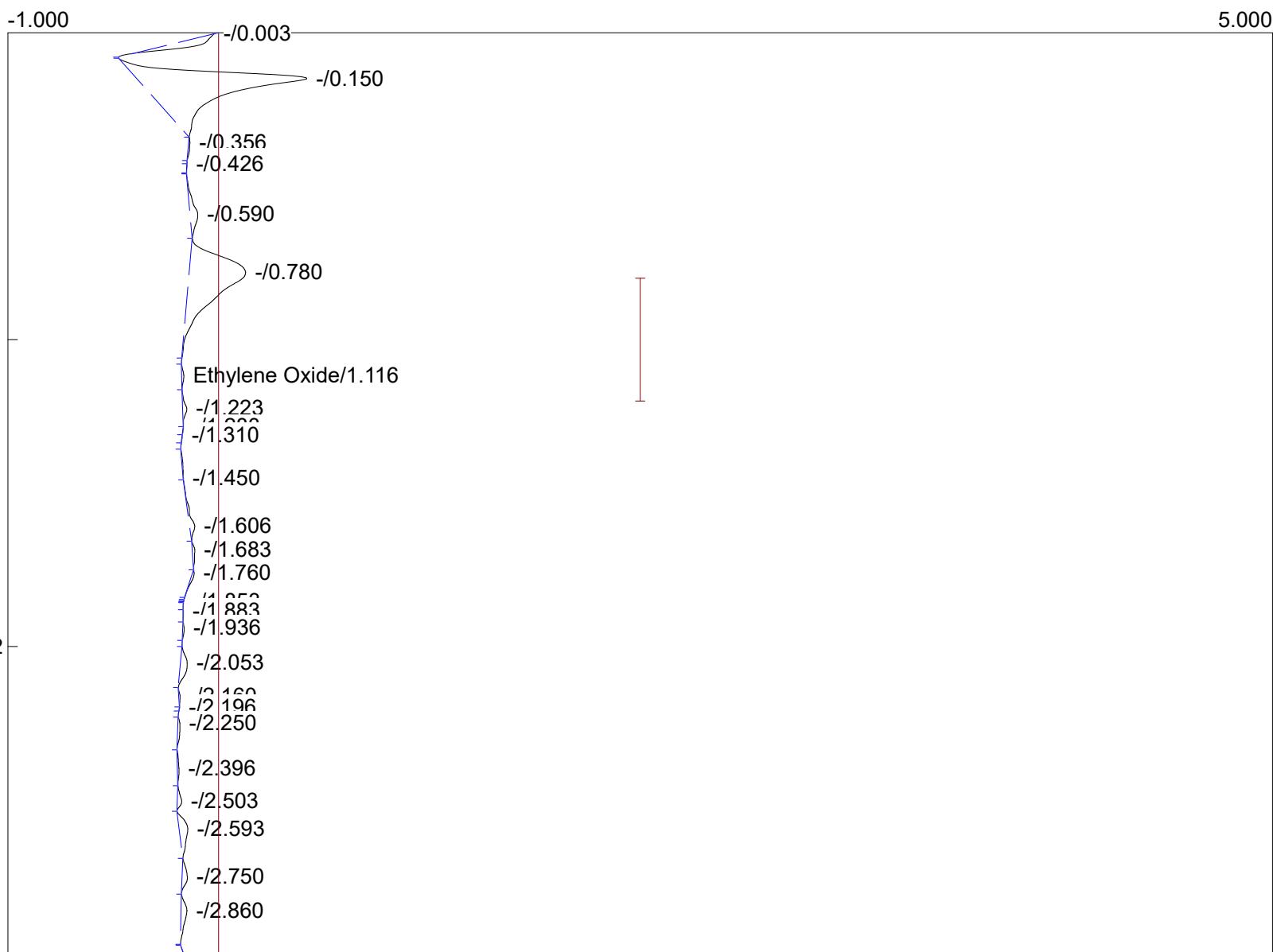
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_943..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 1



Component	Retention	Area
Ethylene Oxide	1.116	0.0245
		0.0245

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 21:07:34

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

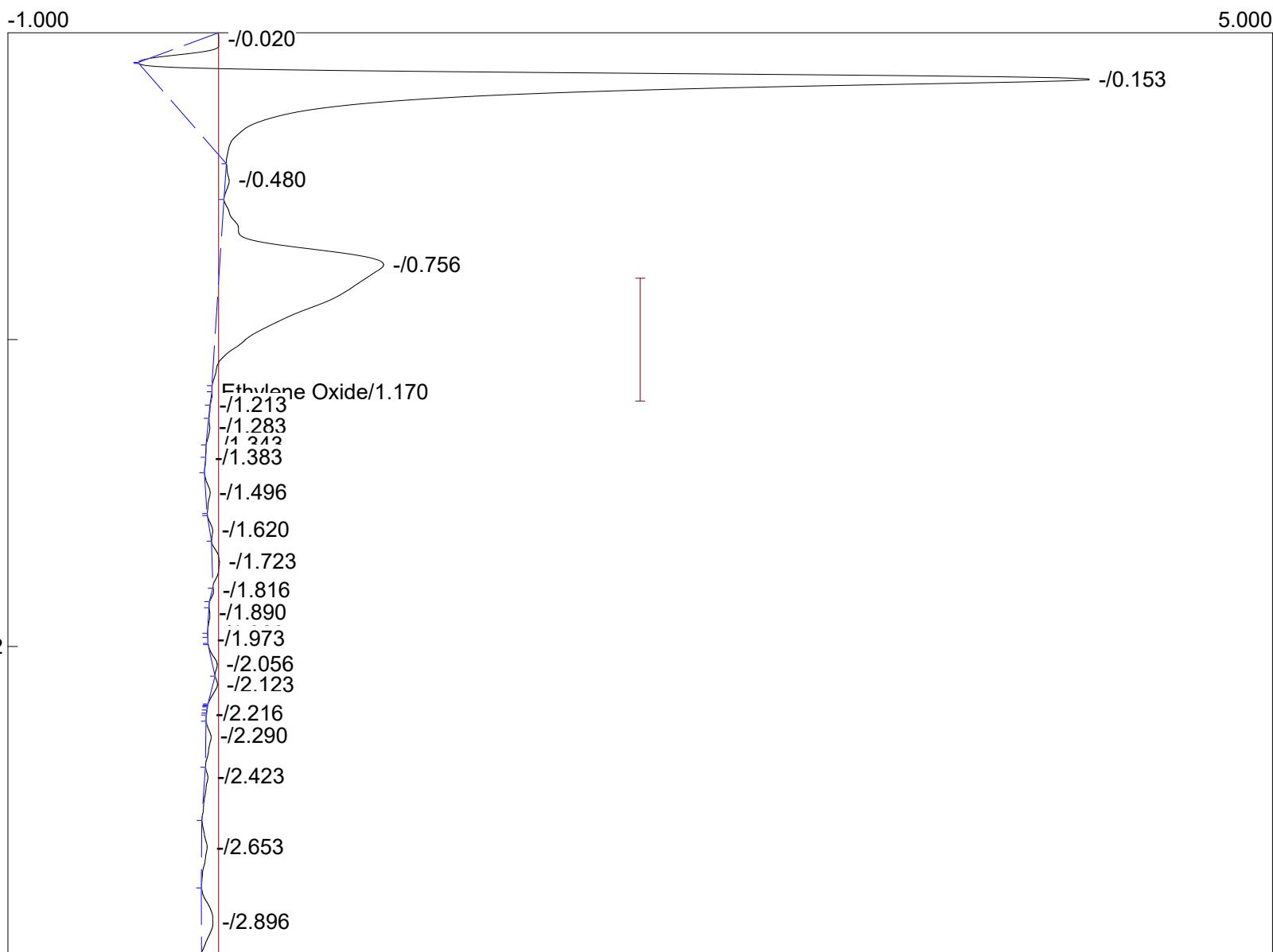
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_944..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 1



Component	Retention	Area
Ethylene Oxide	1.170	0.0045
		0.0045

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 21:11:34

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

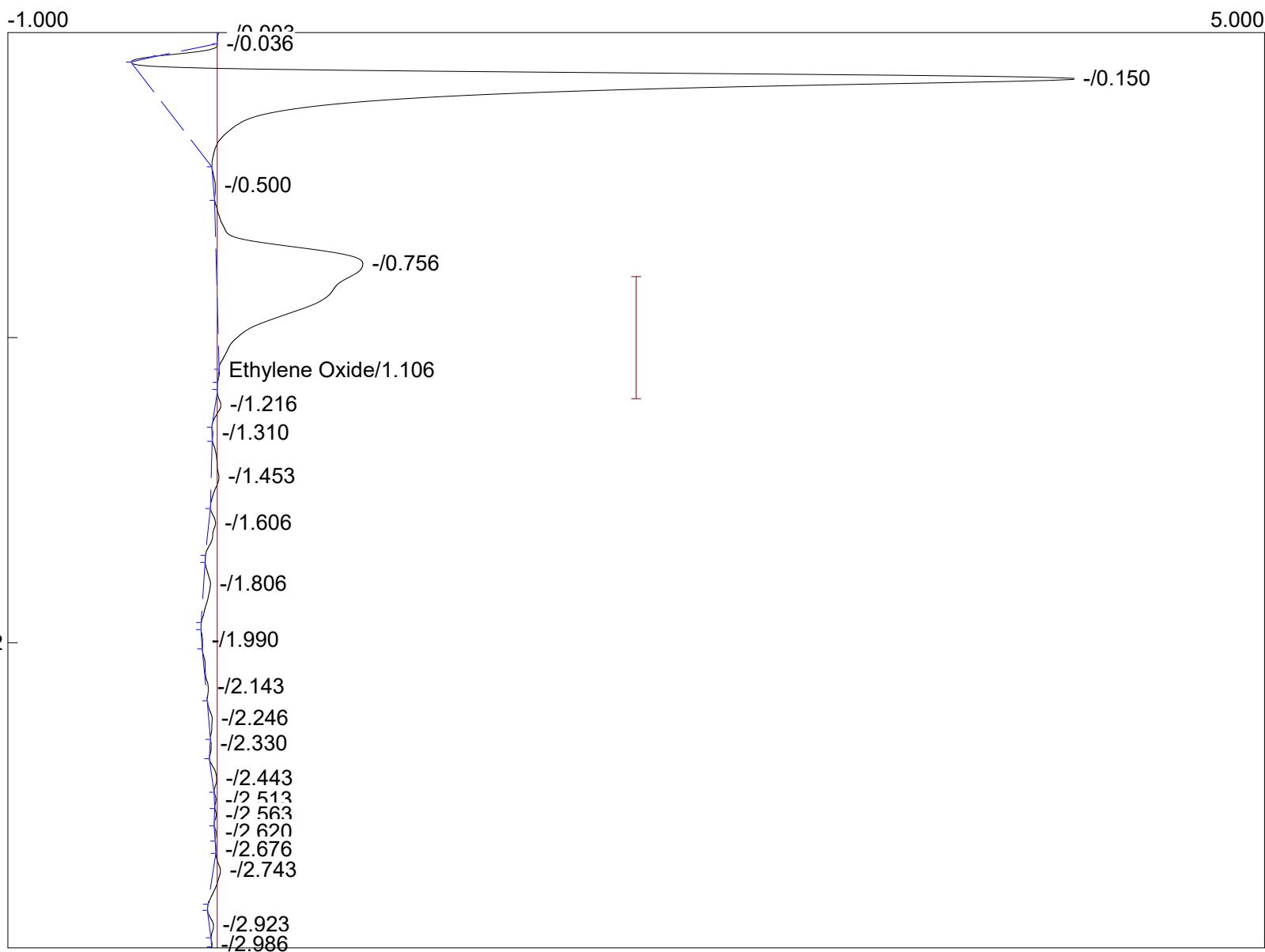
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_945..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 1



Component	Retention	Area
Ethylene Oxide	1.106	0.0057
		0.0057

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 21:15:34

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

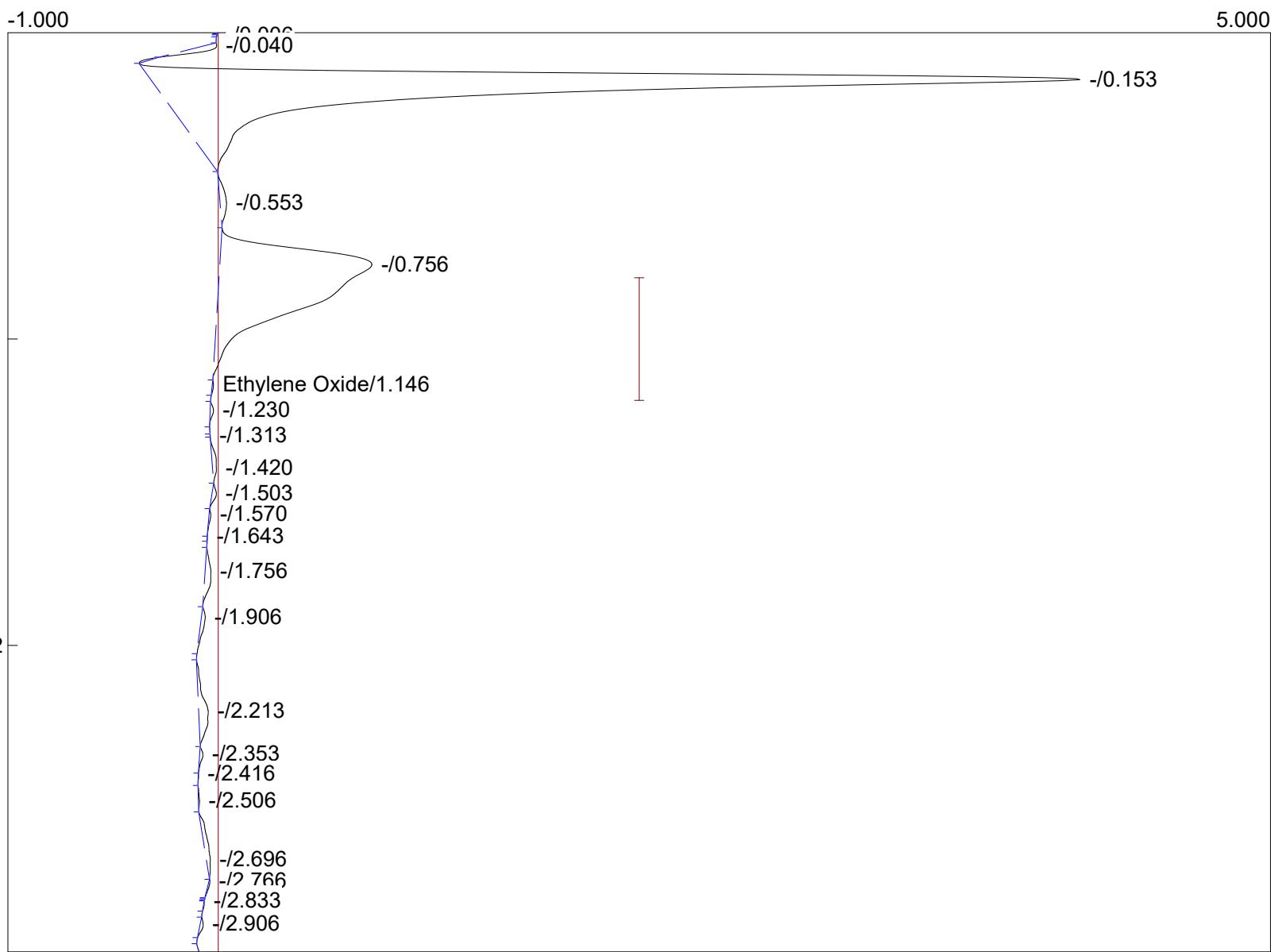
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_946..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 1



Component	Retention	Area
Ethylene Oxide	1.146	0.0108
		0.0108

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 21:19:34

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

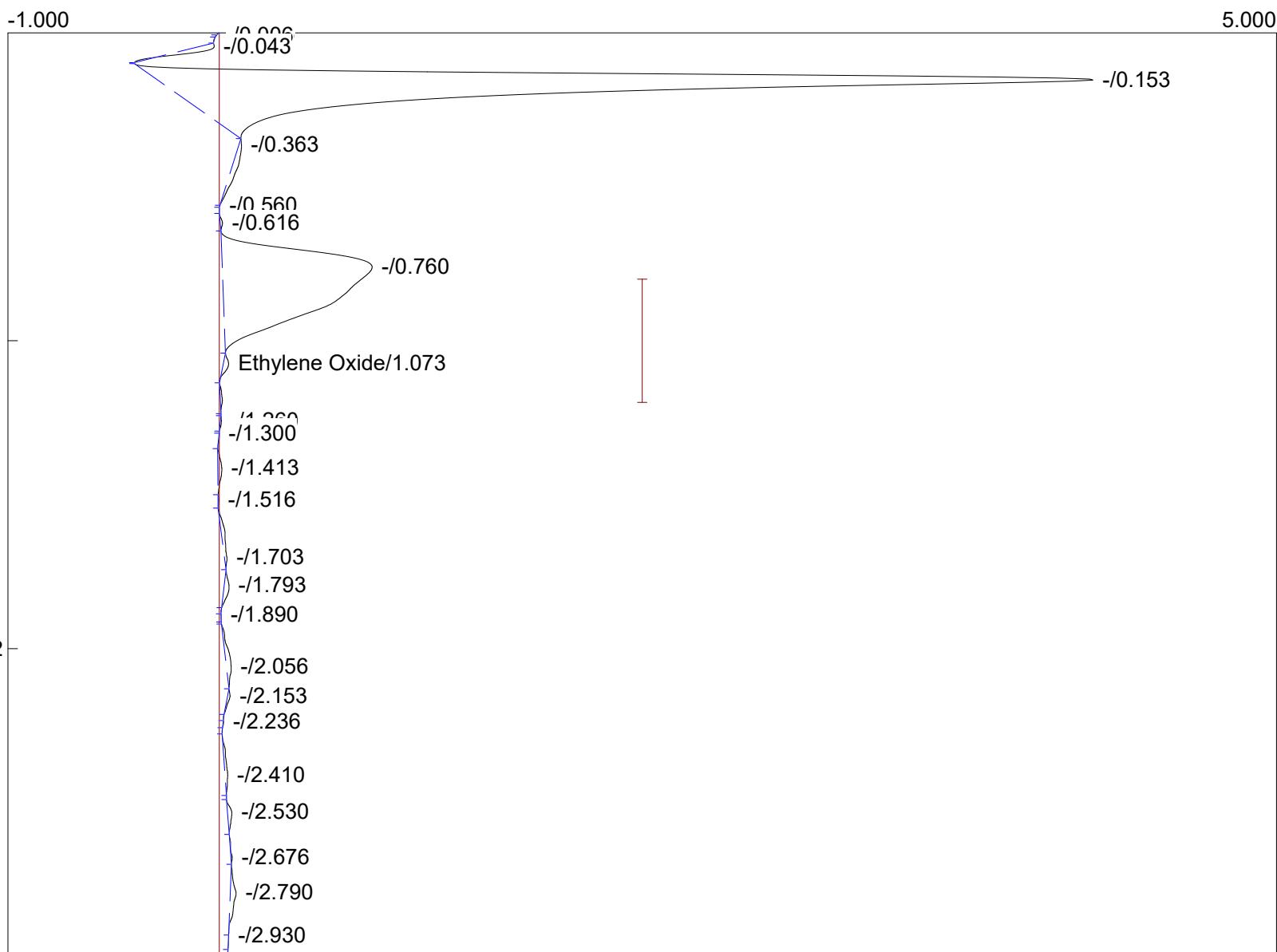
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_947..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 1



Component	Retention	Area
Ethylene Oxide	1.073	0.0710
		0.0710

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 21:23:34

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

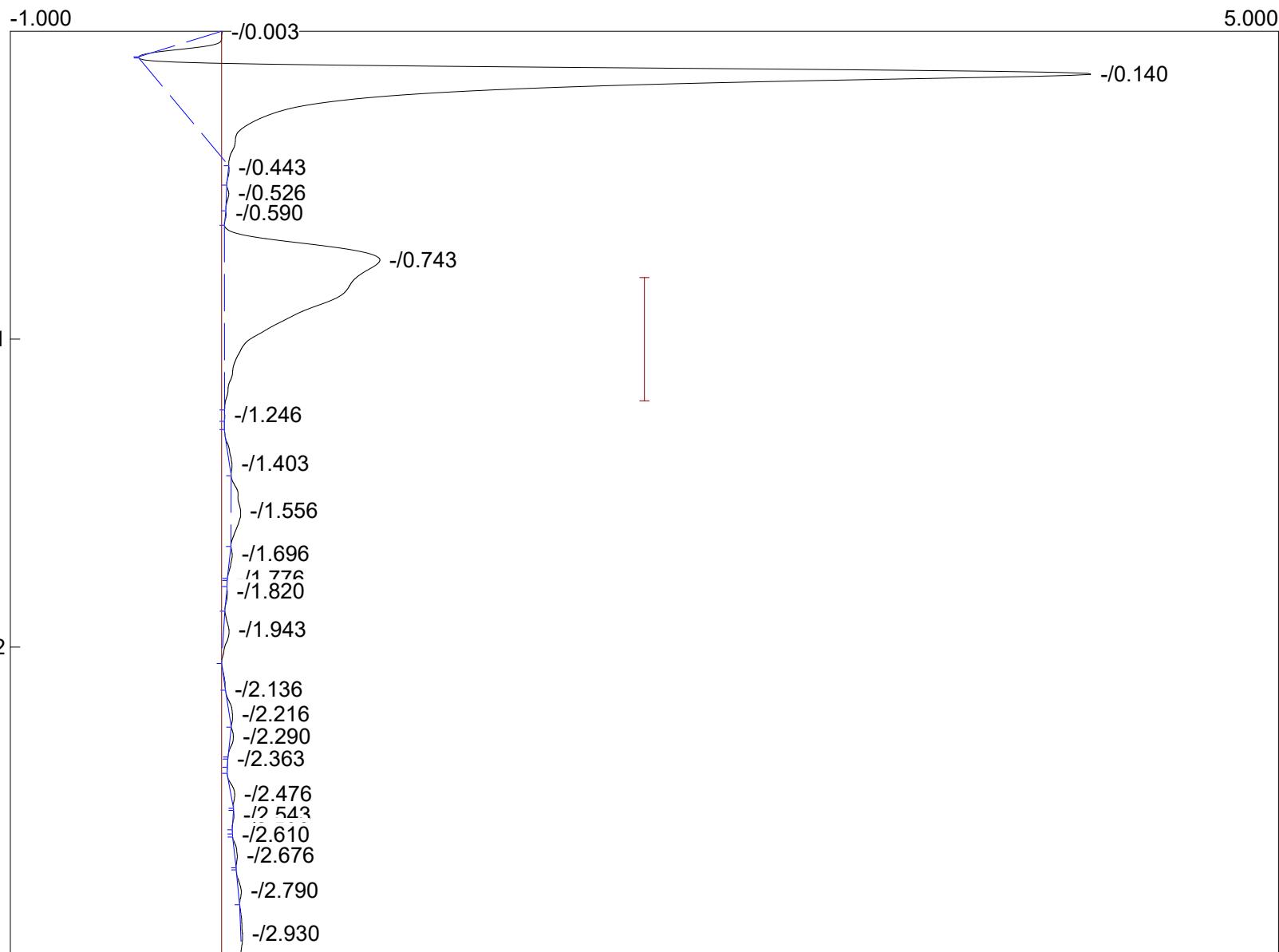
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_948..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 1



Component	Retention	Area
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0.0000

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 21:31:34

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

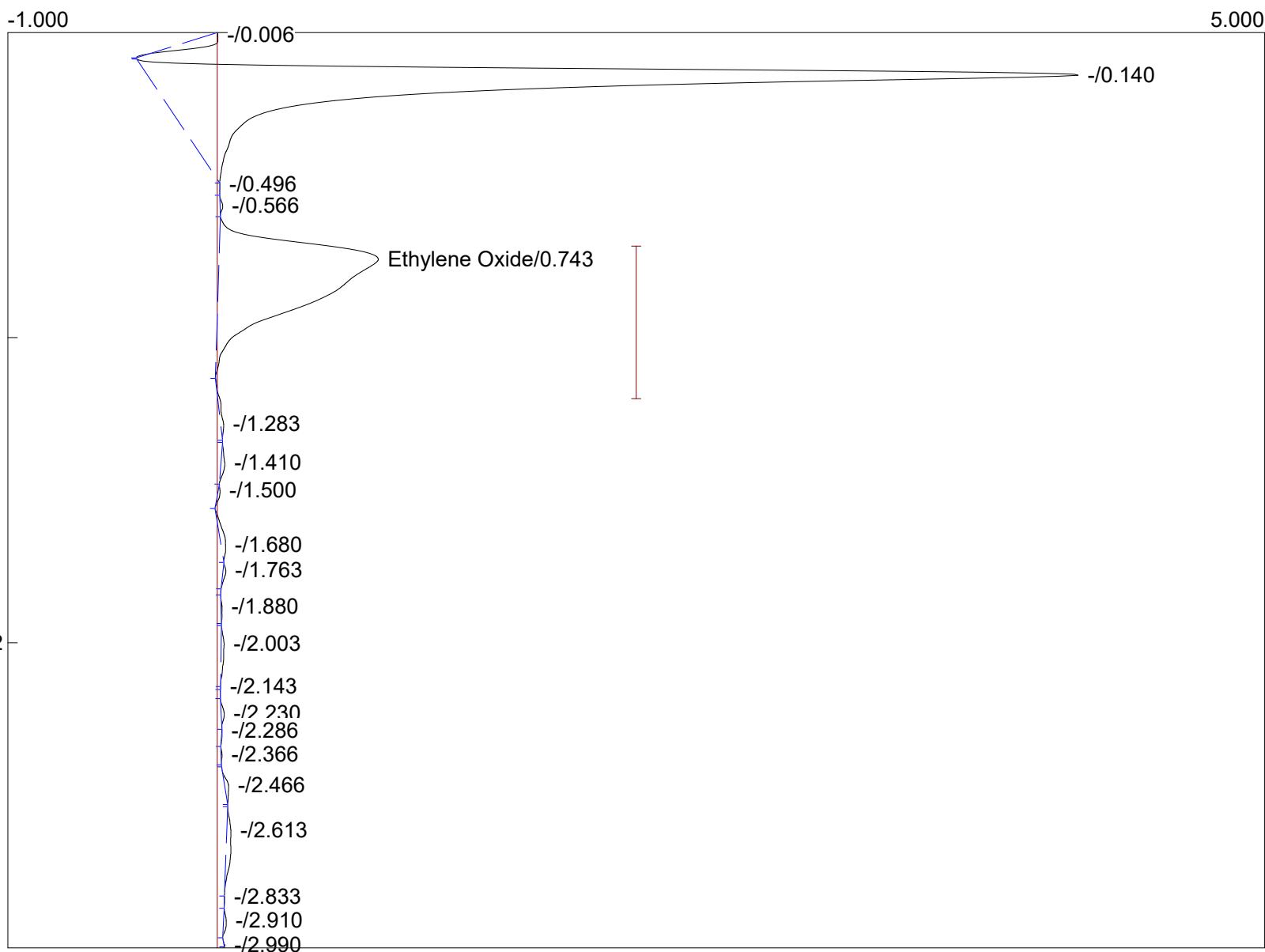
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_950..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 1



Component	Retention	Area
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Ethylene Oxide	0.743	4.7220
		4.7220

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 21:35:34

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

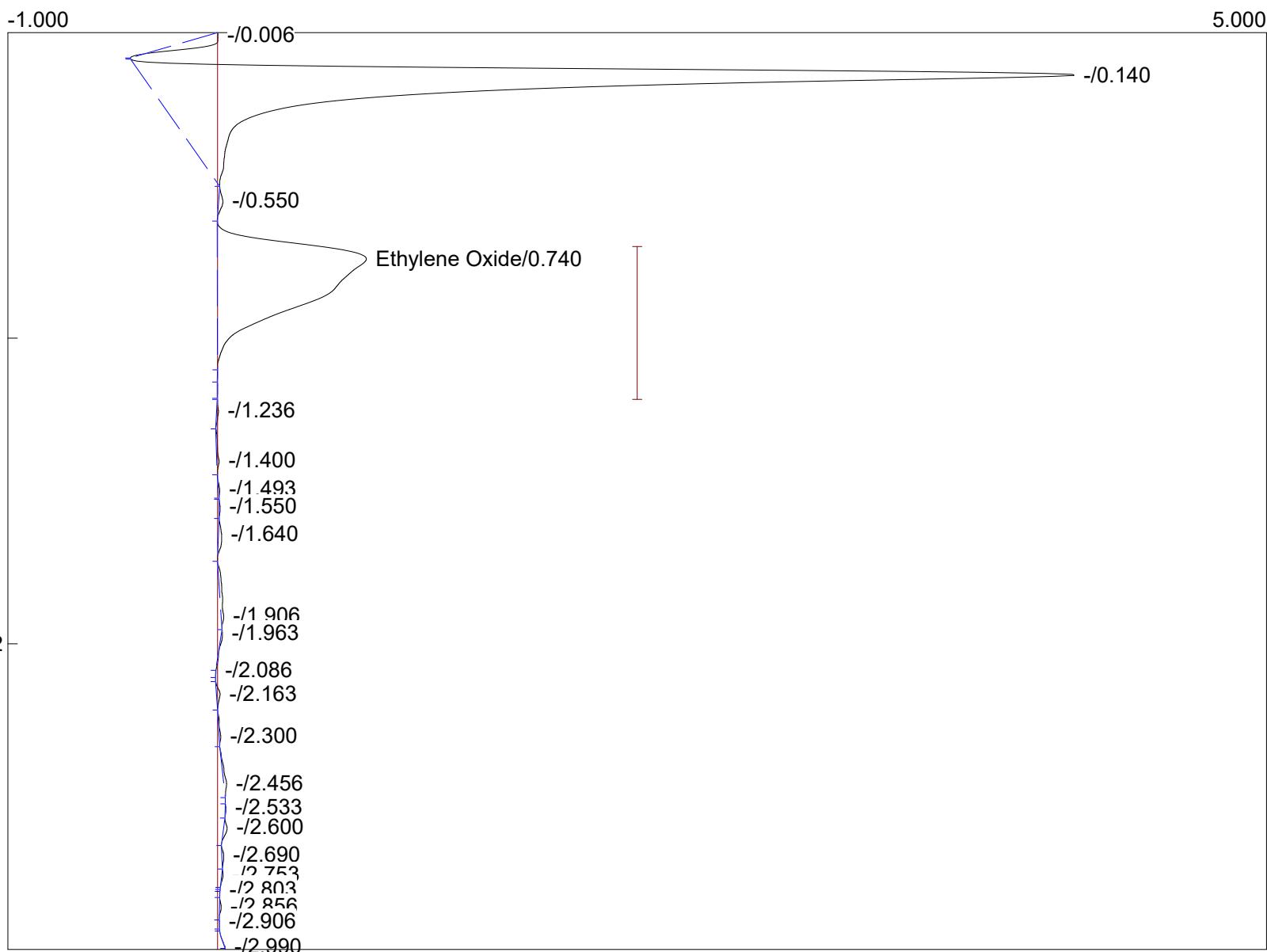
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_951..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 1



Component	Retention	Area
Ethylene Oxide	0.740	4.0366
		4.0366

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 21:39:34

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

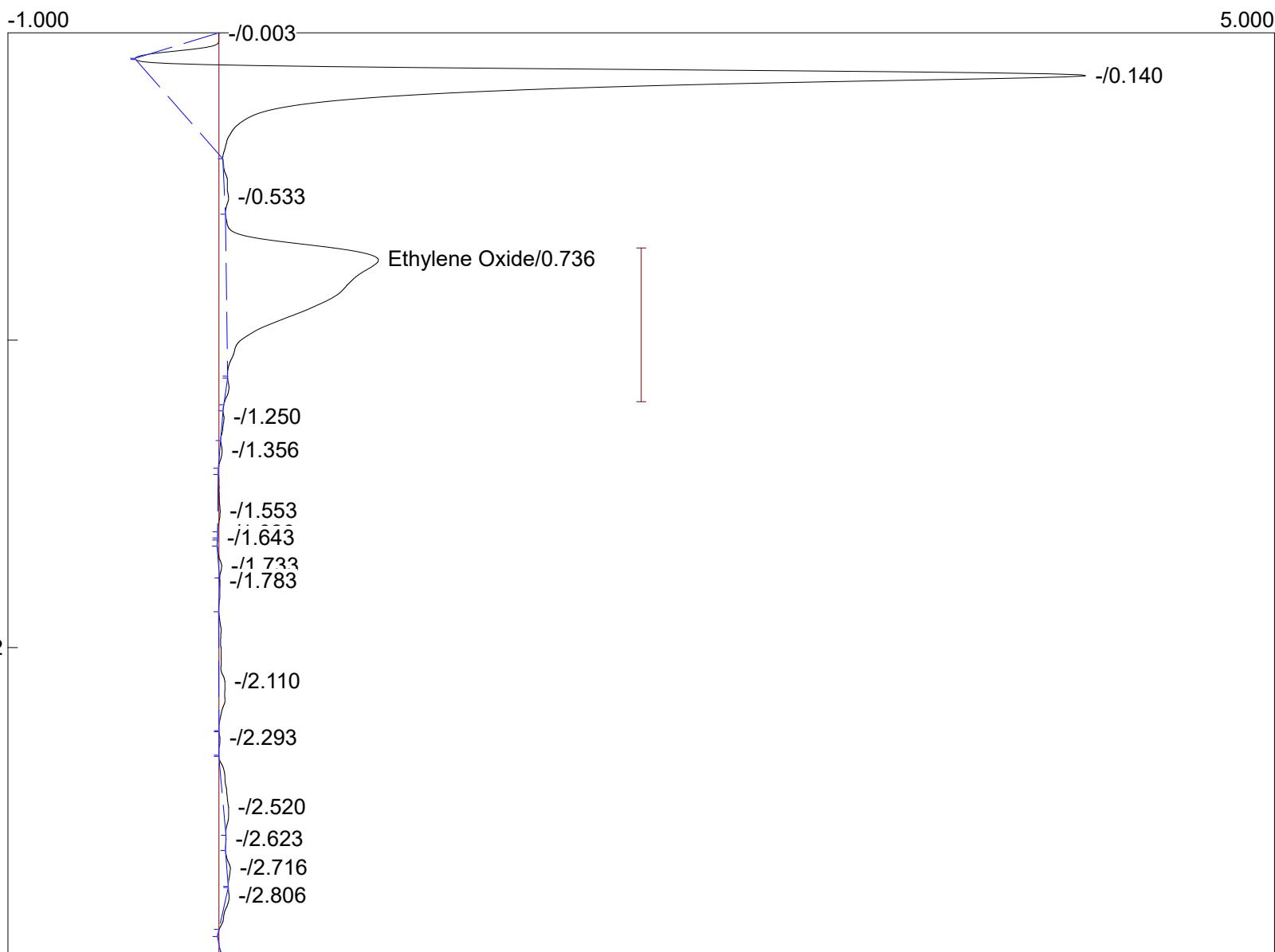
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_952..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 1



Component	Retention	Area
Ethylene Oxide	0.736	4.2074
		4.2074

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 21:43:34

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

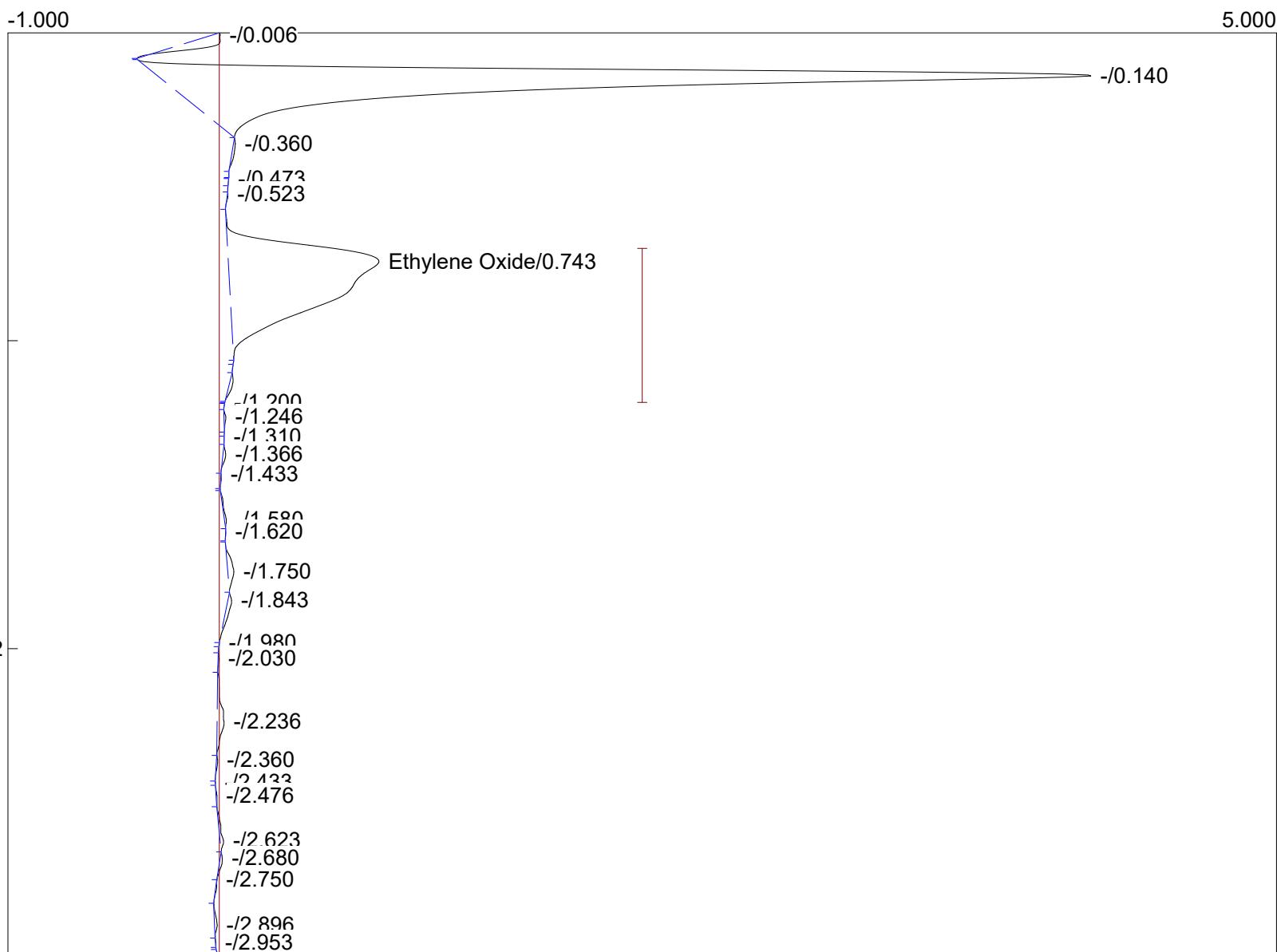
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_953..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 1



Component	Retention	Area
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Ethylene Oxide	0.743	3.9635
		3.9635

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 21:47:34

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

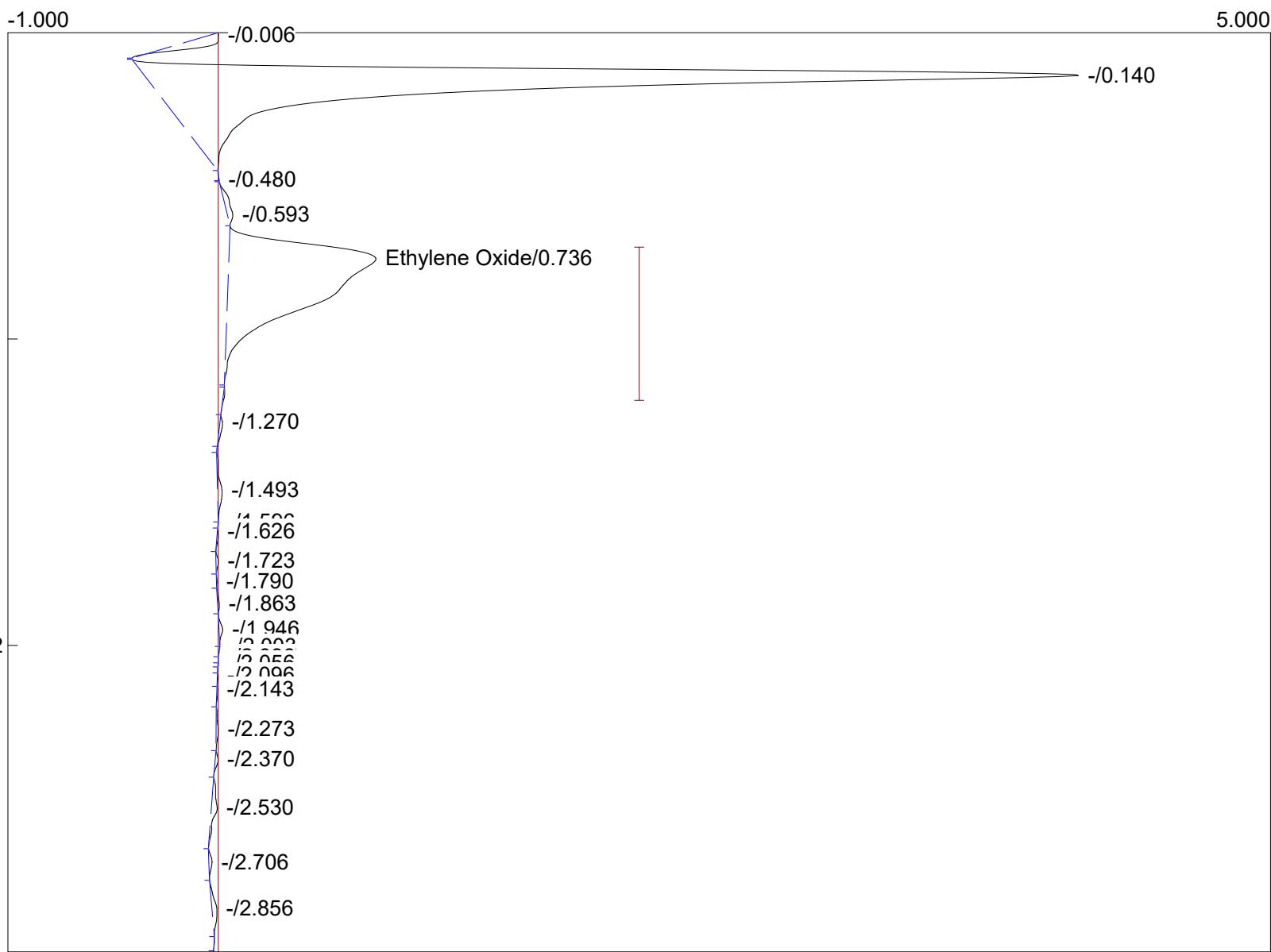
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_954..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 1



Component	Retention	Area
Ethylene Oxide	0.736	3.8808
		3.8808

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 21:59:34

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

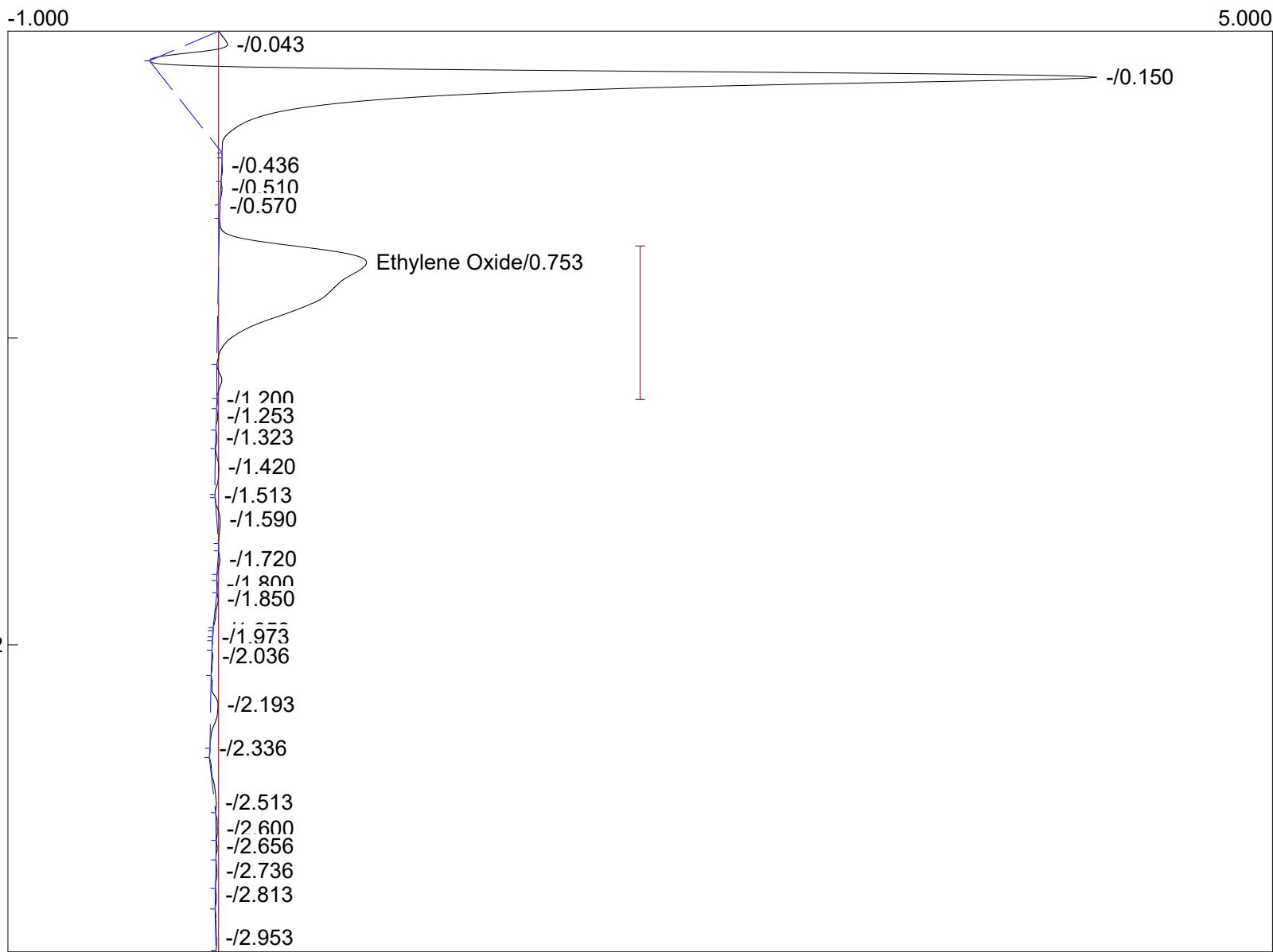
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_957..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 1



Component	Retention	Area
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Ethylene Oxide	0.753	3.7207
		3.7207

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 22:03:34

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

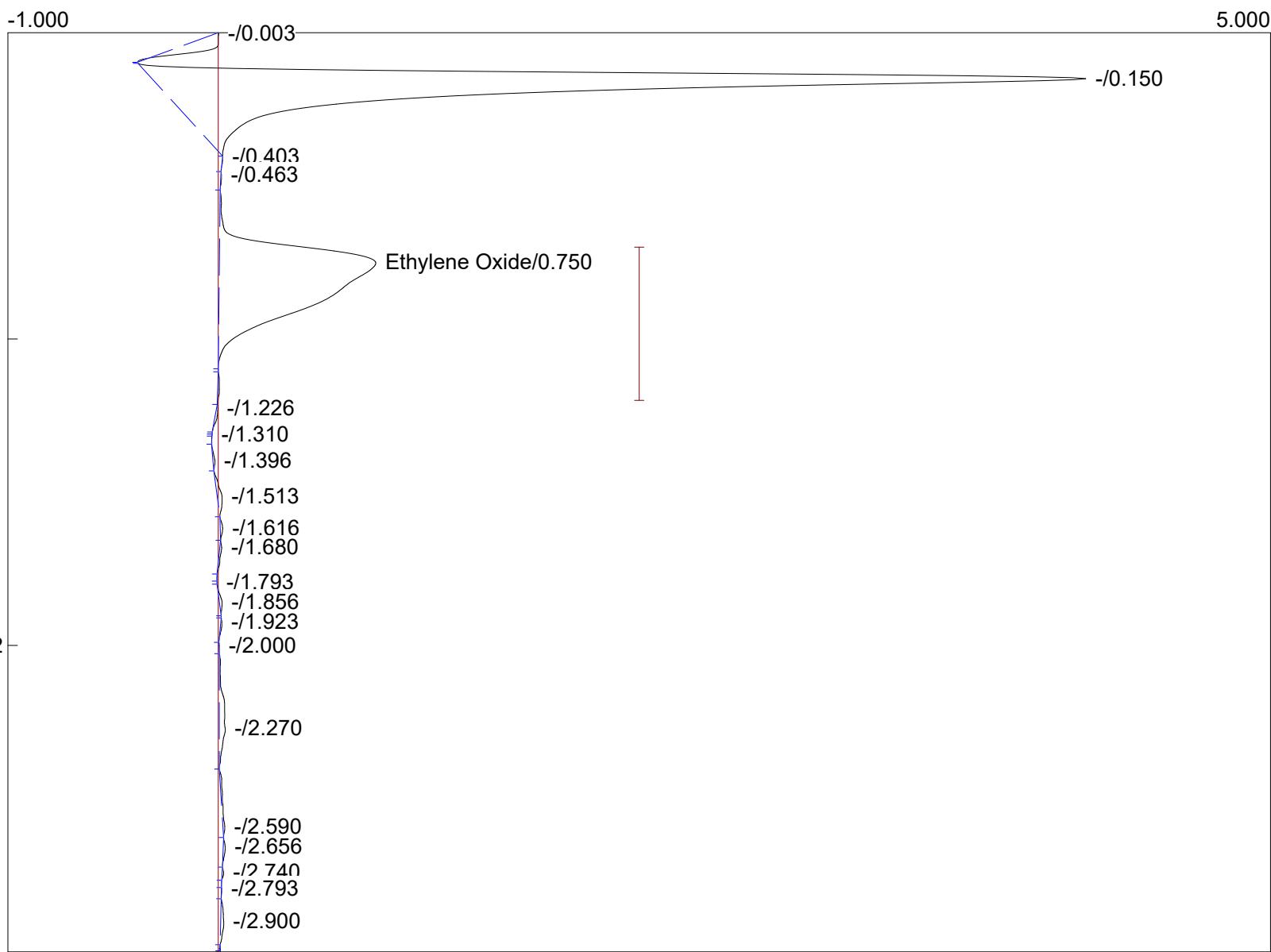
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_958..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 1



Component	Retention	Area
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Ethylene Oxide	0.750	4.2847
		4.2847

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 22:07:34

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

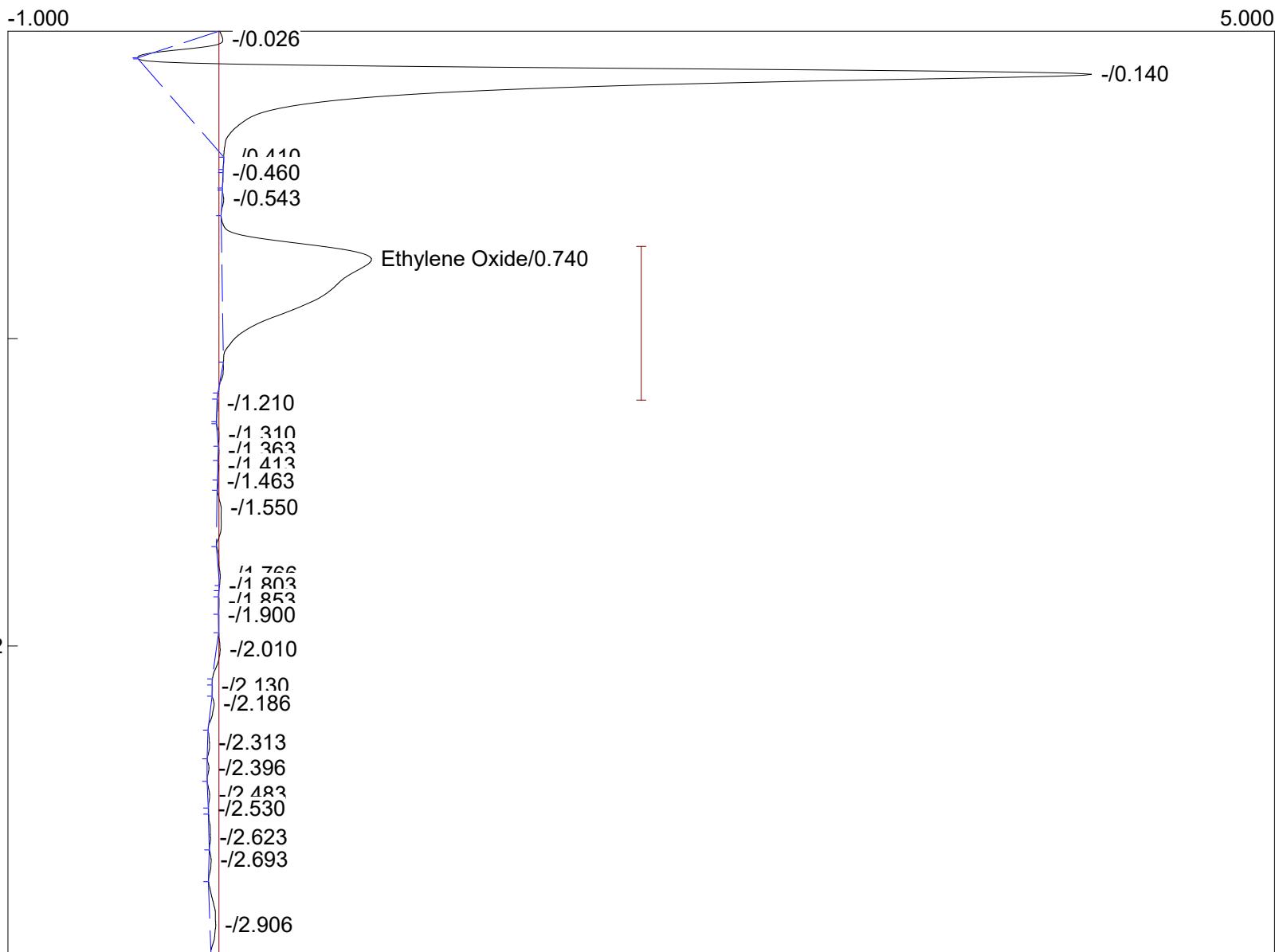
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_959..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 2



Component	Retention	Area
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Ethylene Oxide	0.740	3.6765
		3.6765

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 22:11:34

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

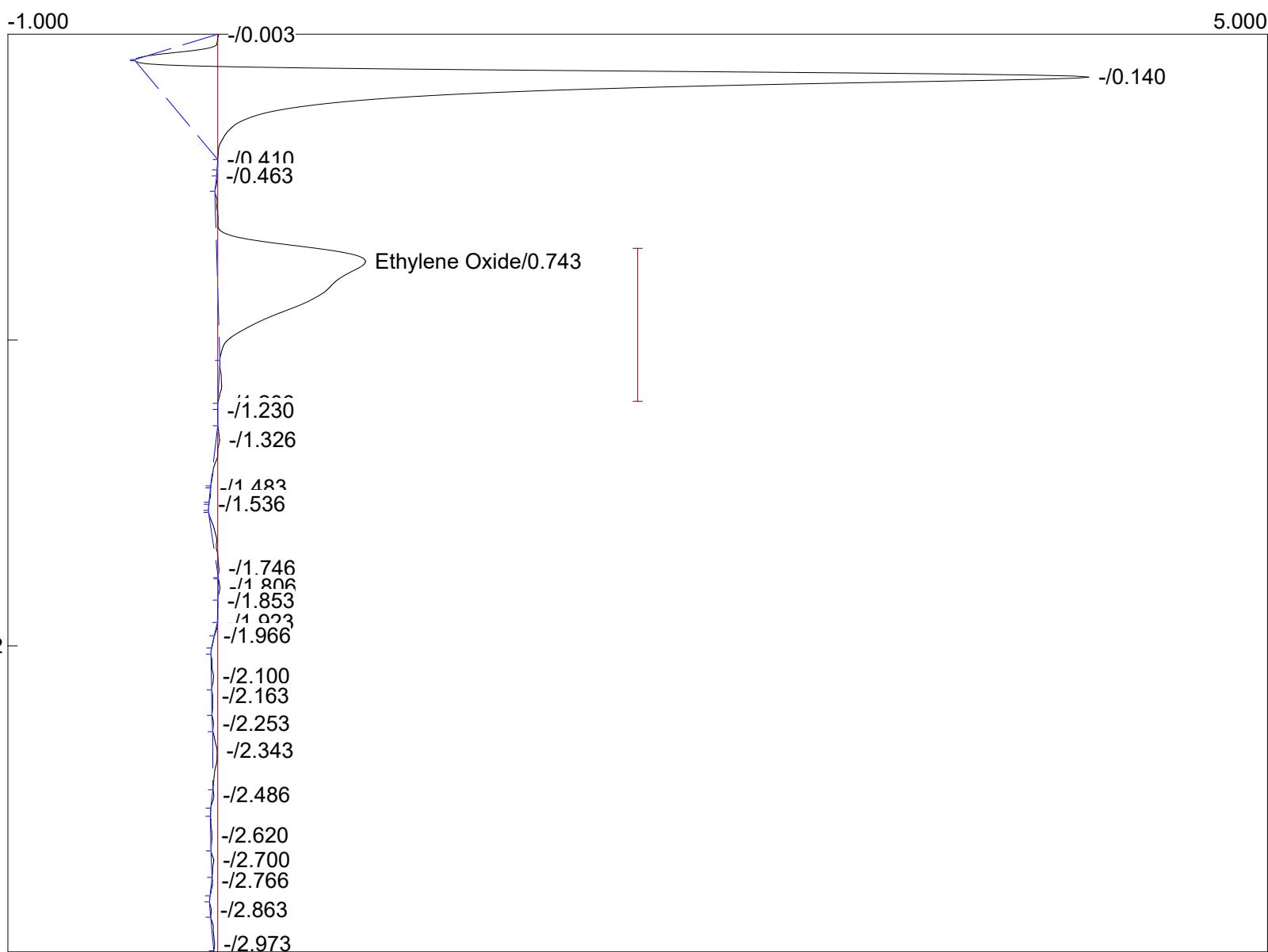
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_960..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 2



Component	Retention	Area
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Ethylene Oxide	0.743	3.5402
		3.5402

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 22:15:35

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

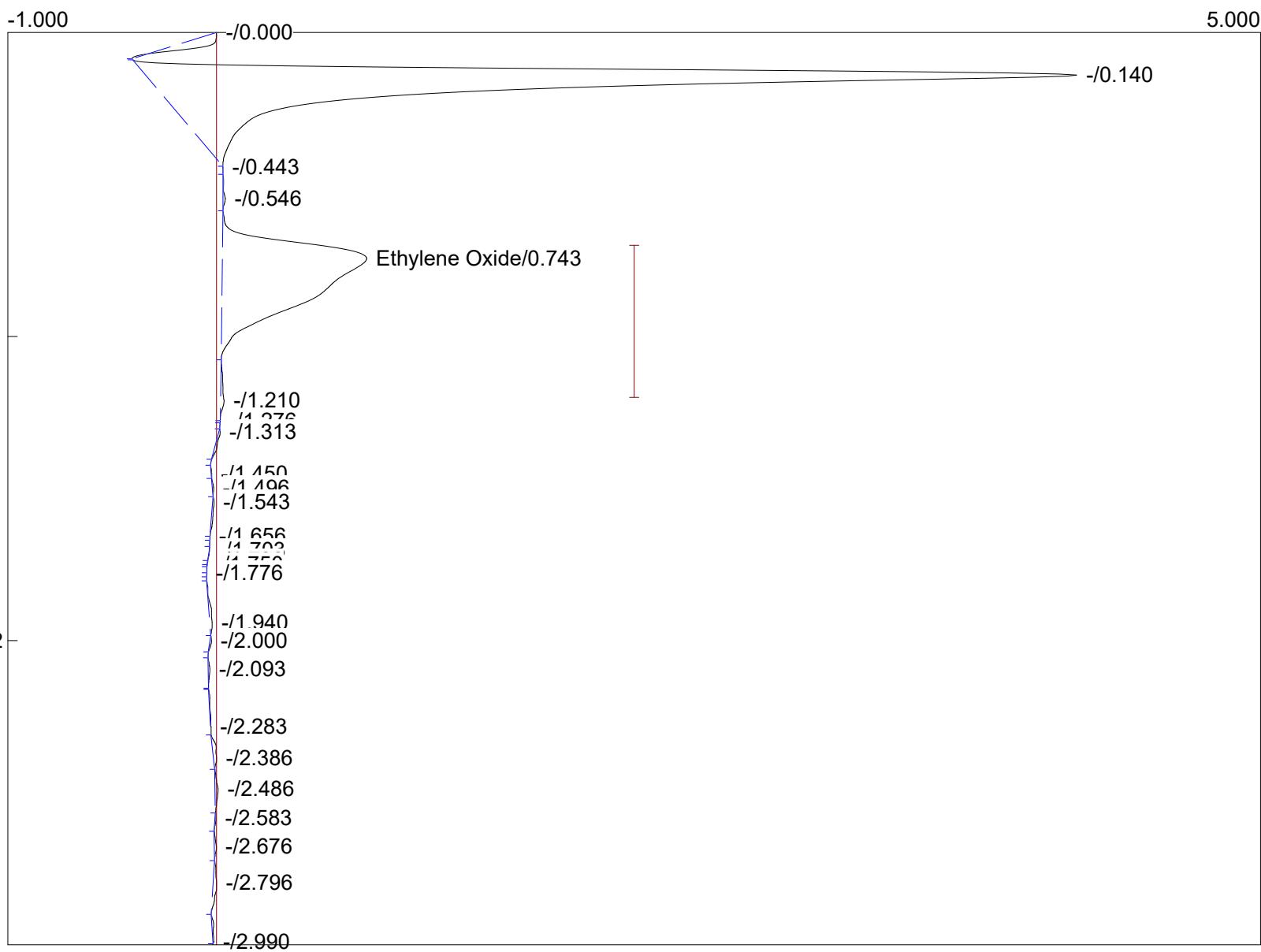
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_961..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 2



Component	Retention	Area
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Ethylene Oxide	0.743	3.5765
		3.5765

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 22:19:35

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

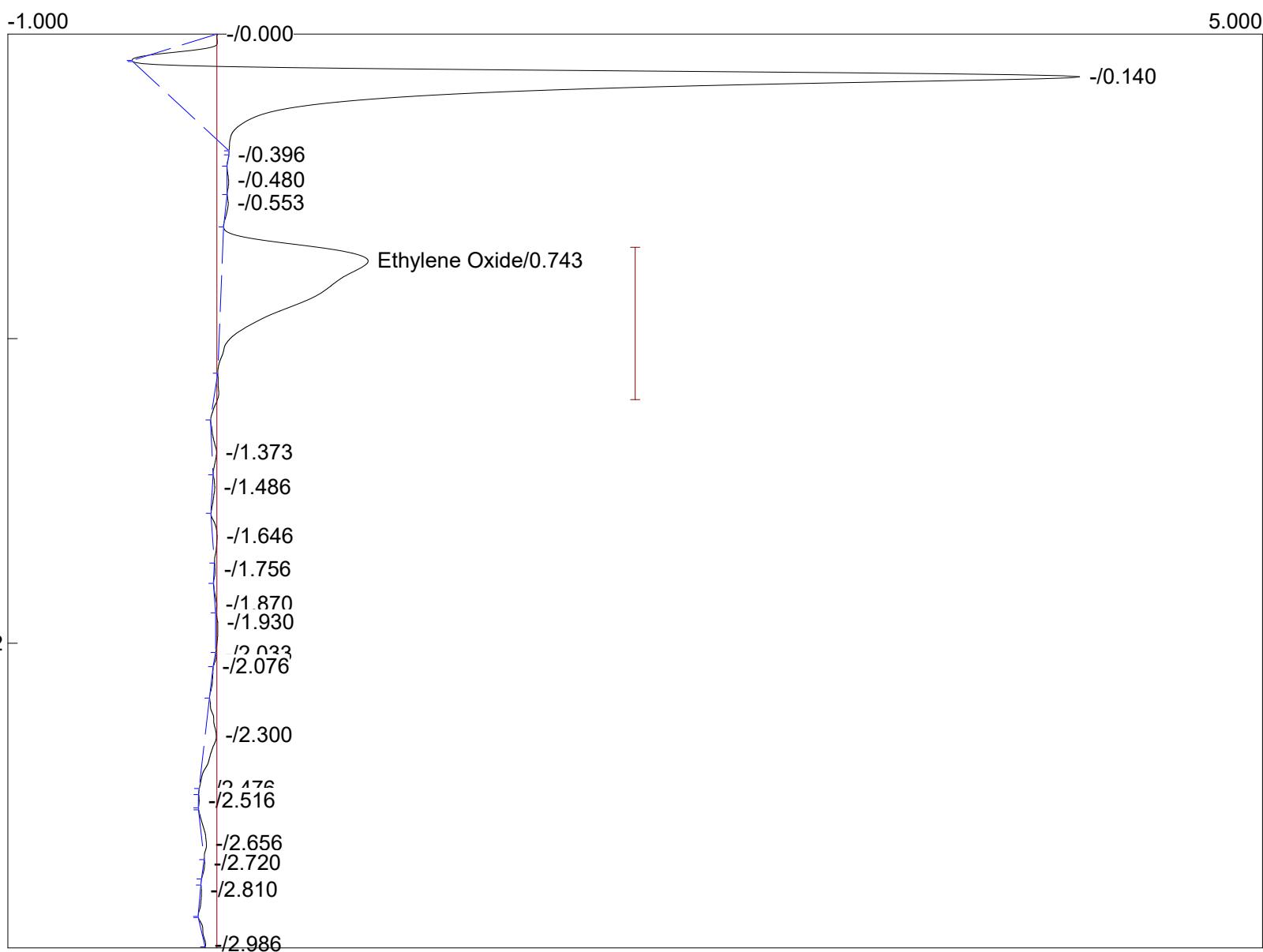
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_962..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 2



Component	Retention	Area
Ethylene Oxide	0.743	3.3196
		3.3196

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 22:27:35

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

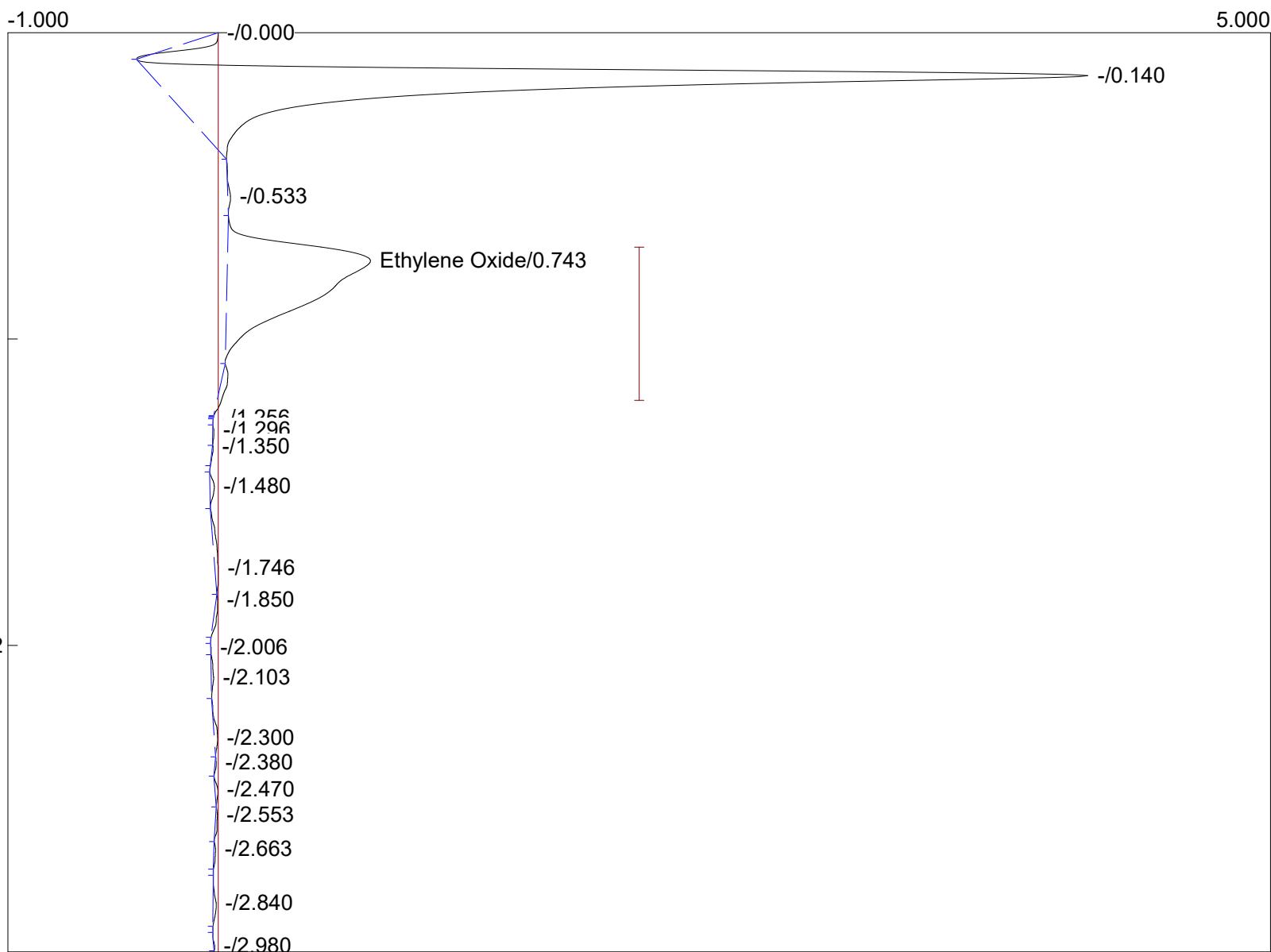
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_964..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 2



Component	Retention	Area
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Ethylene Oxide	0.743	3.2937
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		3.2937
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Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 22:31:35

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

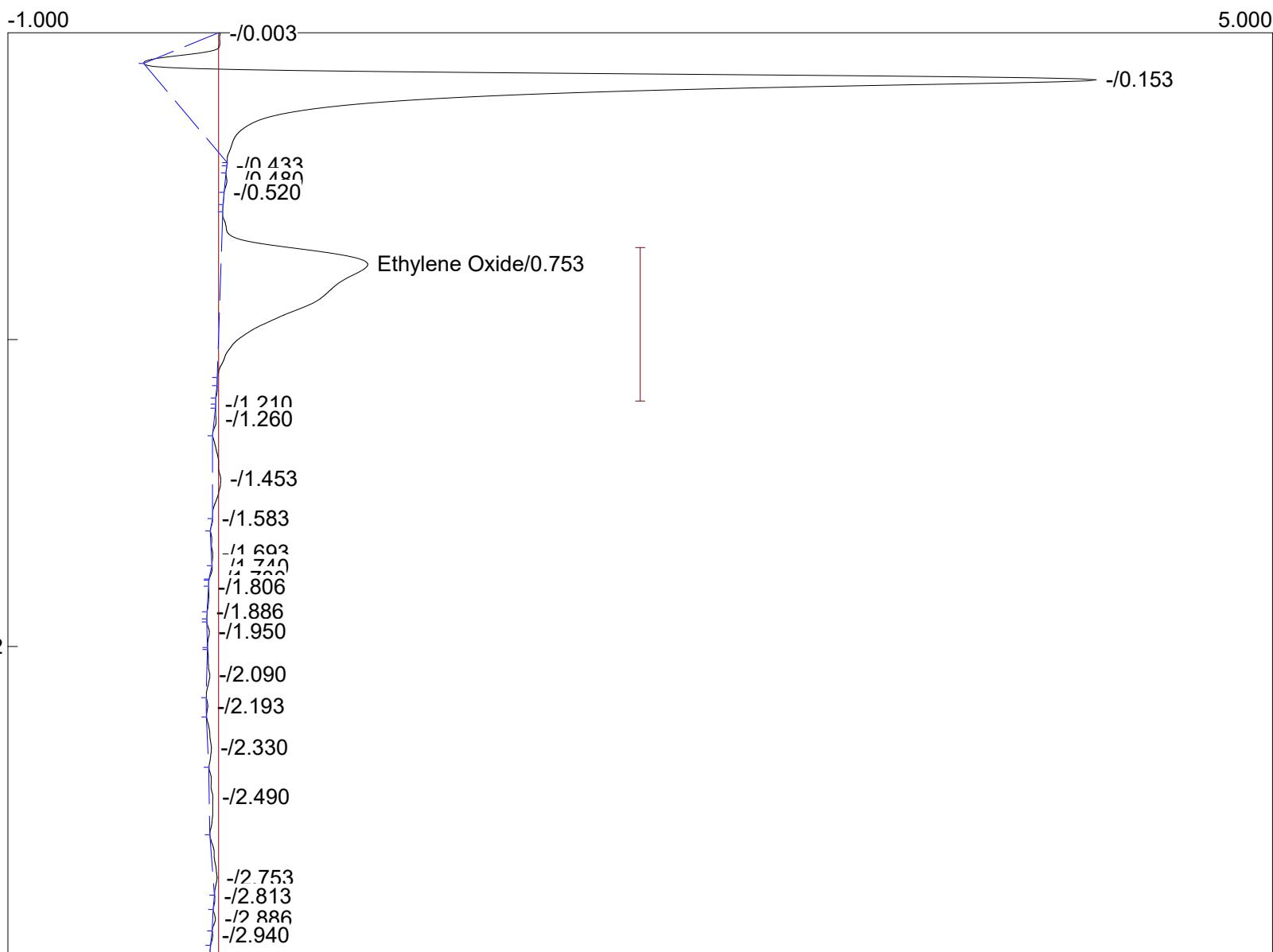
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_965..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 2



Component	Retention	Area
Ethylene Oxide	0.753	3.6320
		3.6320

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 22:35:35

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

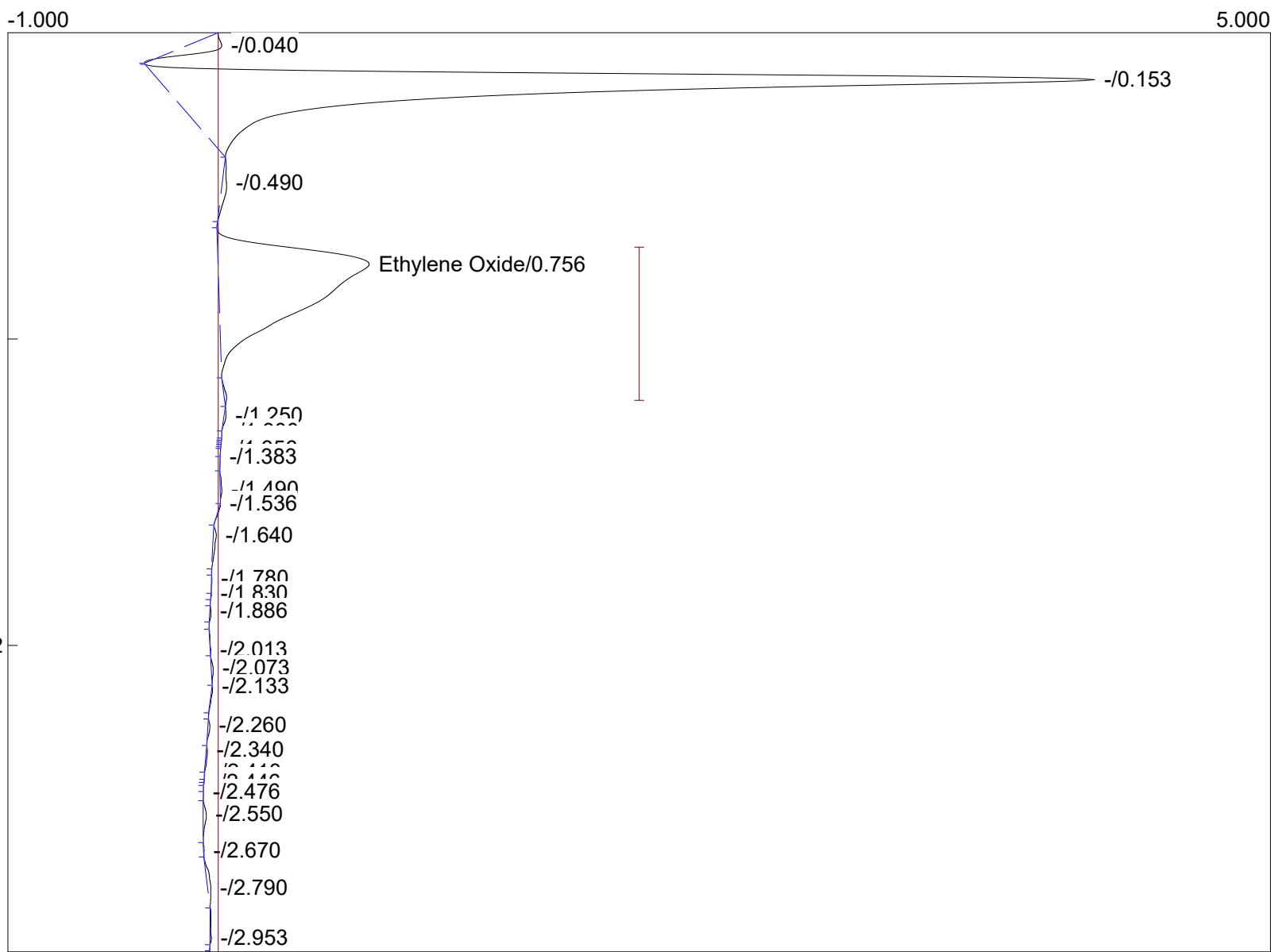
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_966..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 2



Component	Retention	Area
Ethylene Oxide	0.756	4.0763
		4.0763

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 22:39:35

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

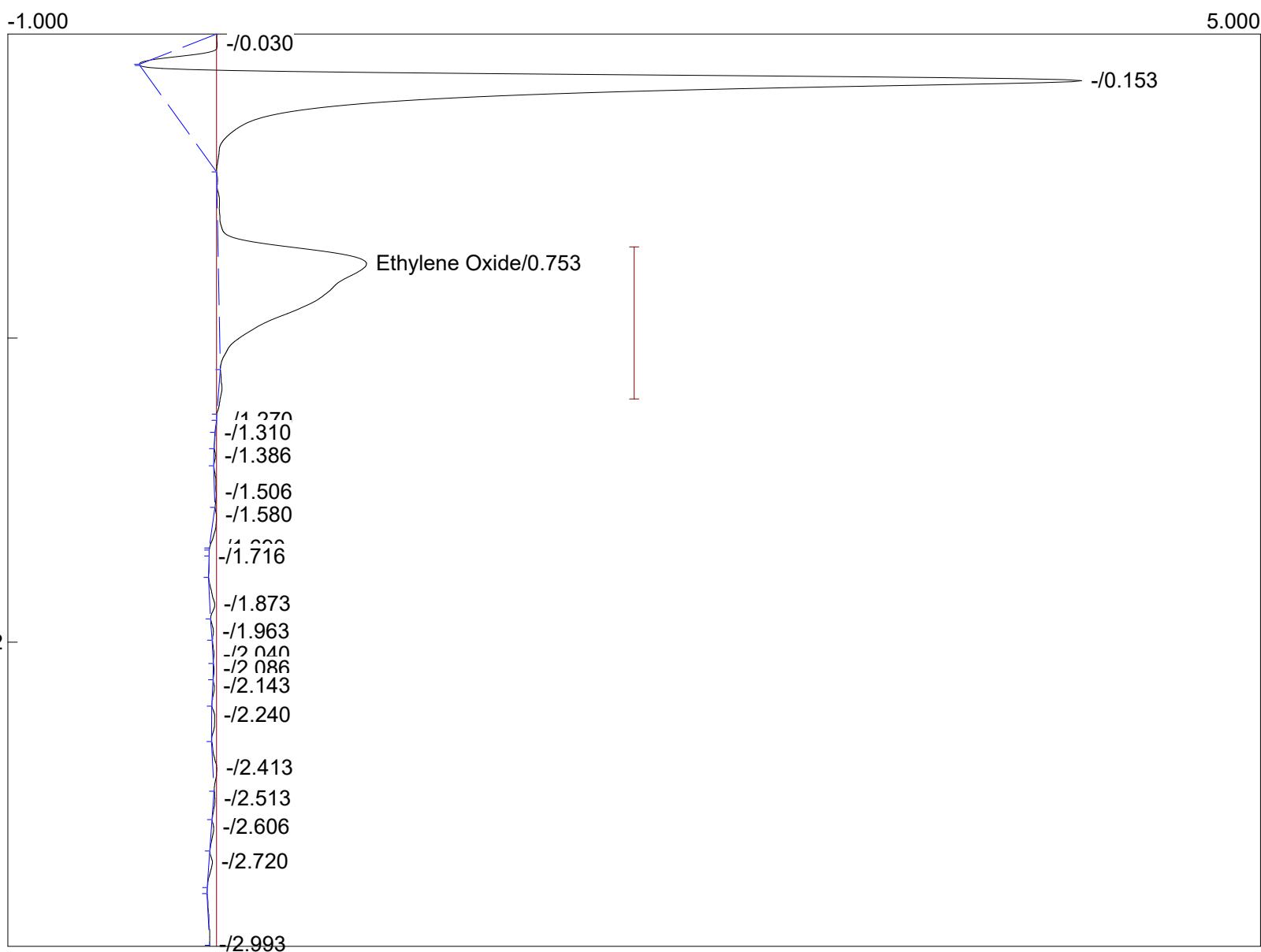
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_967..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 2



Component	Retention	Area
Ethylene Oxide	0.753	3.9118
		3.9118

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 22:43:35

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

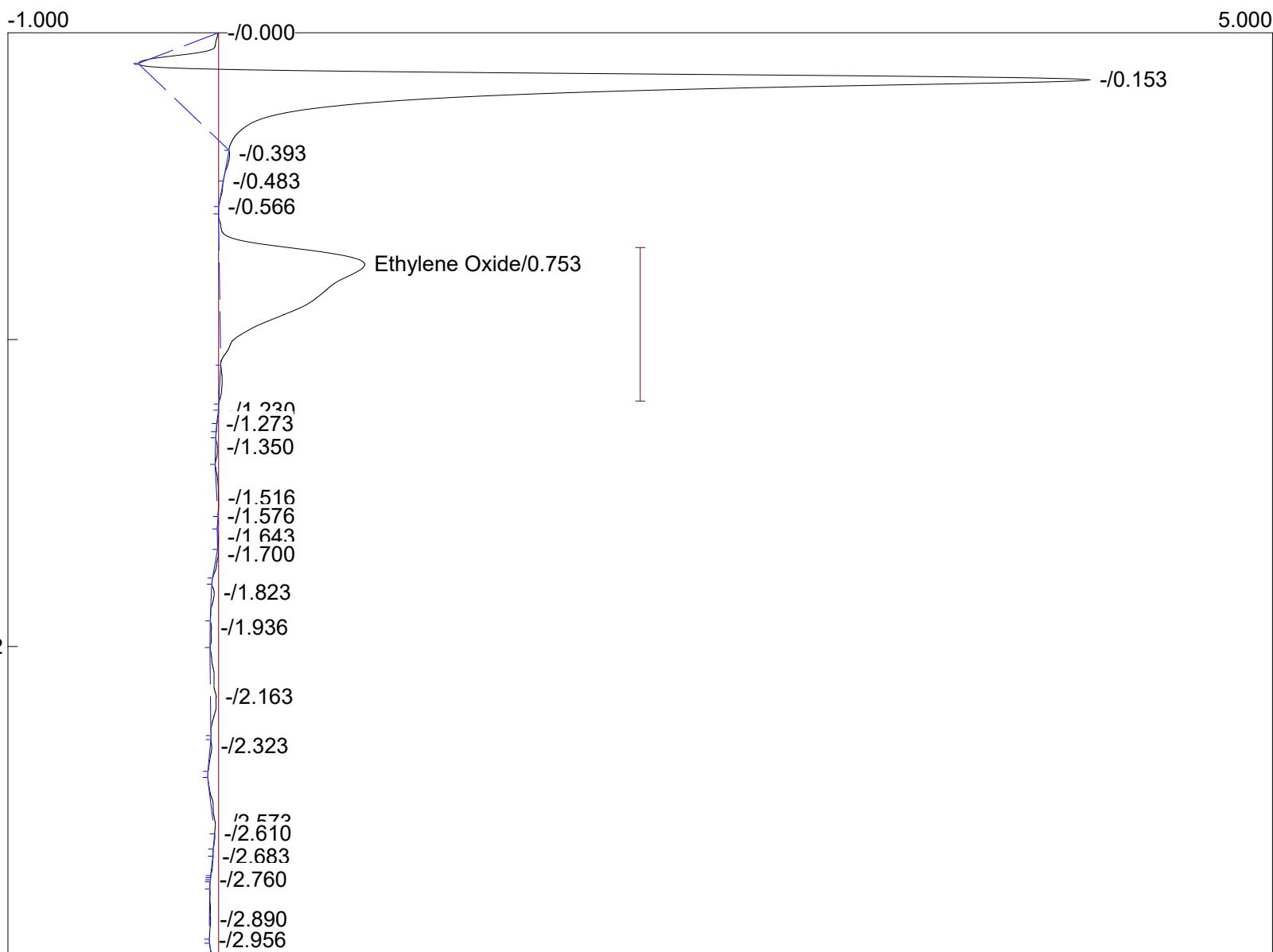
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_968..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 2



Component	Retention	Area
Ethylene Oxide	0.753	3.2680
		3.2680

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 22:47:35

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

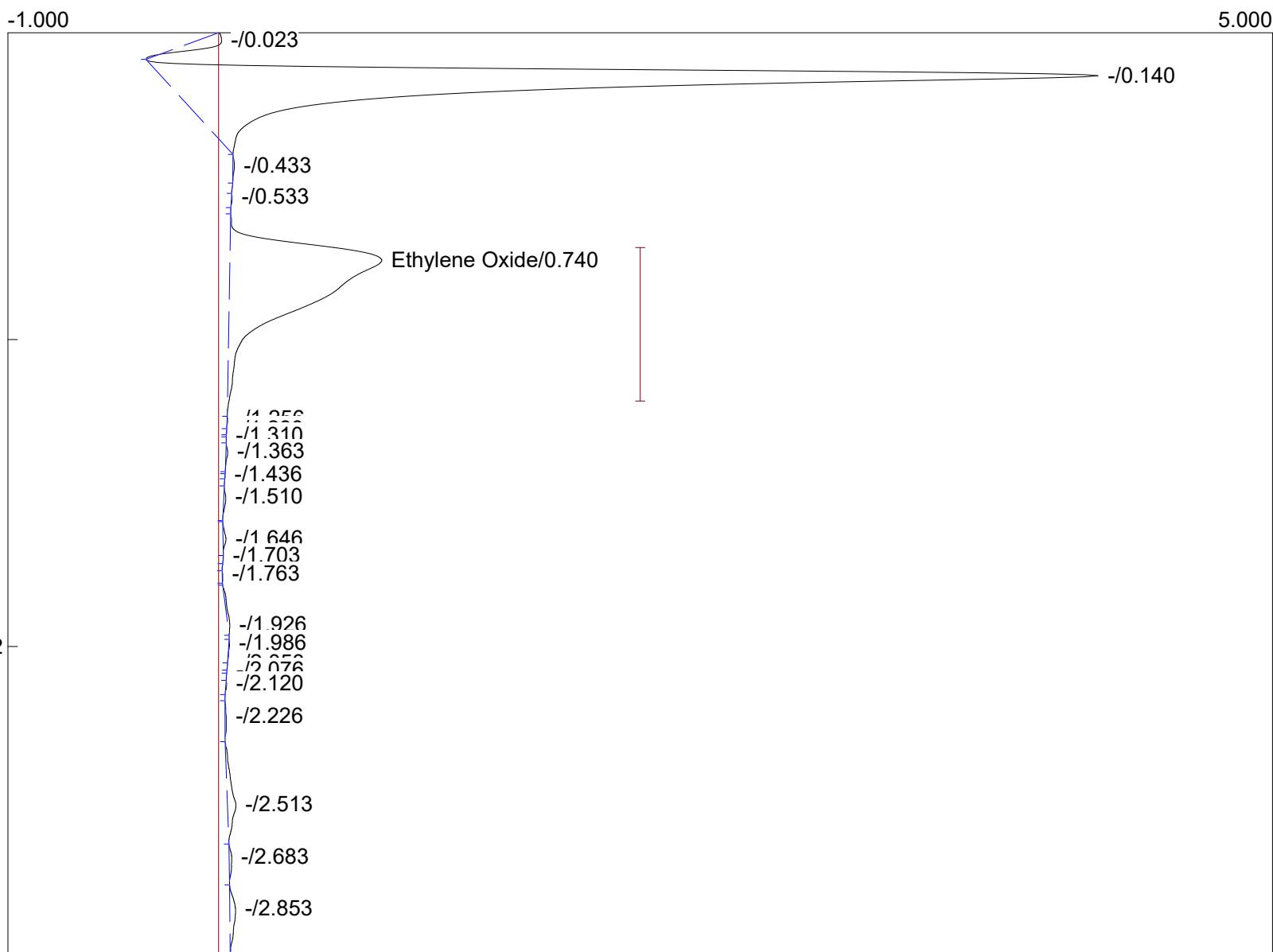
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_969..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 2



Component	Retention	Area
Ethylene Oxide	0.740	3.8742
		3.8742

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 22:51:35

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

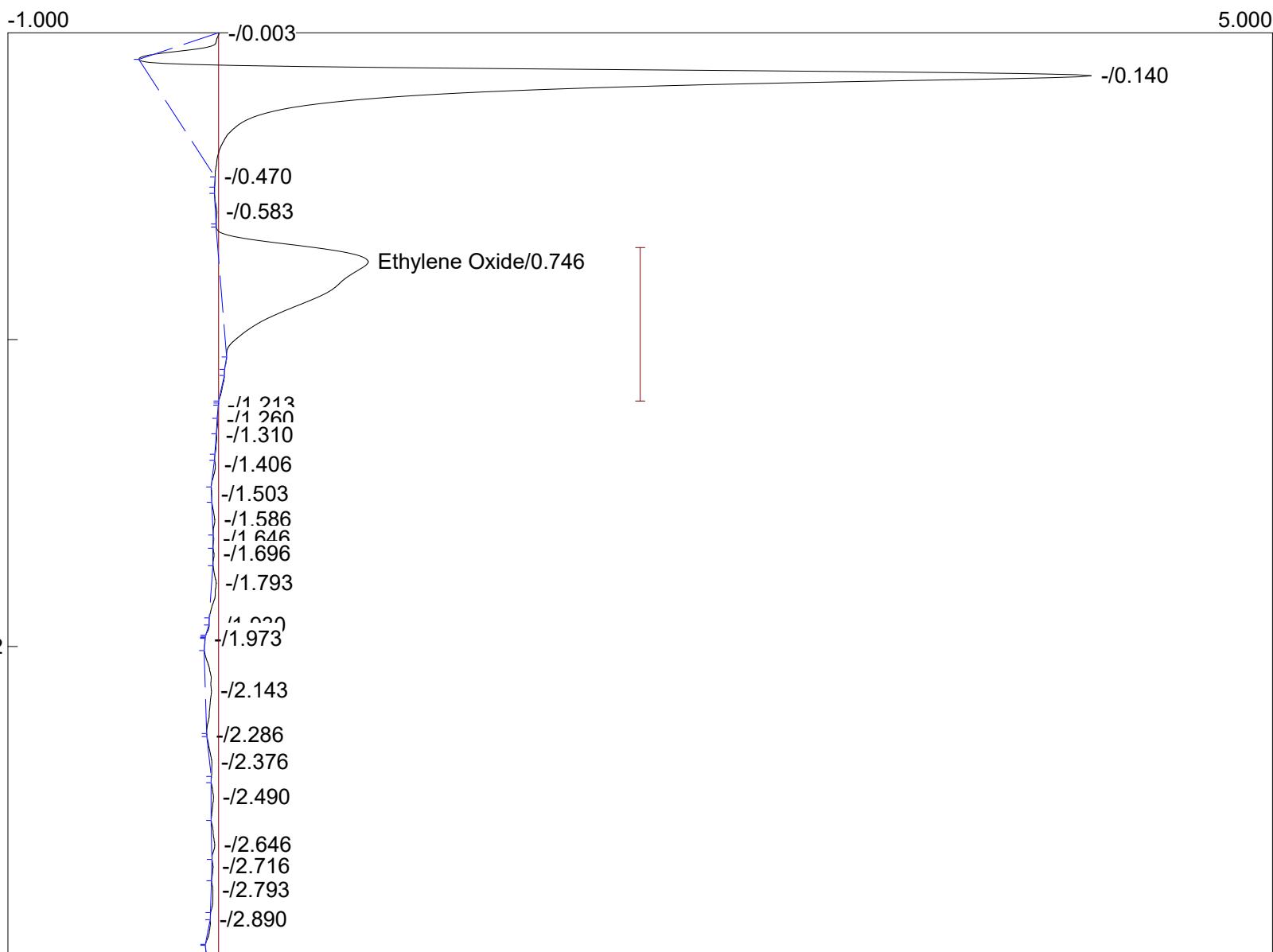
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_970..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 2



Component	Retention	Area
Ethylene Oxide	0.746	3.3550
		3.3550

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 22:55:35

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

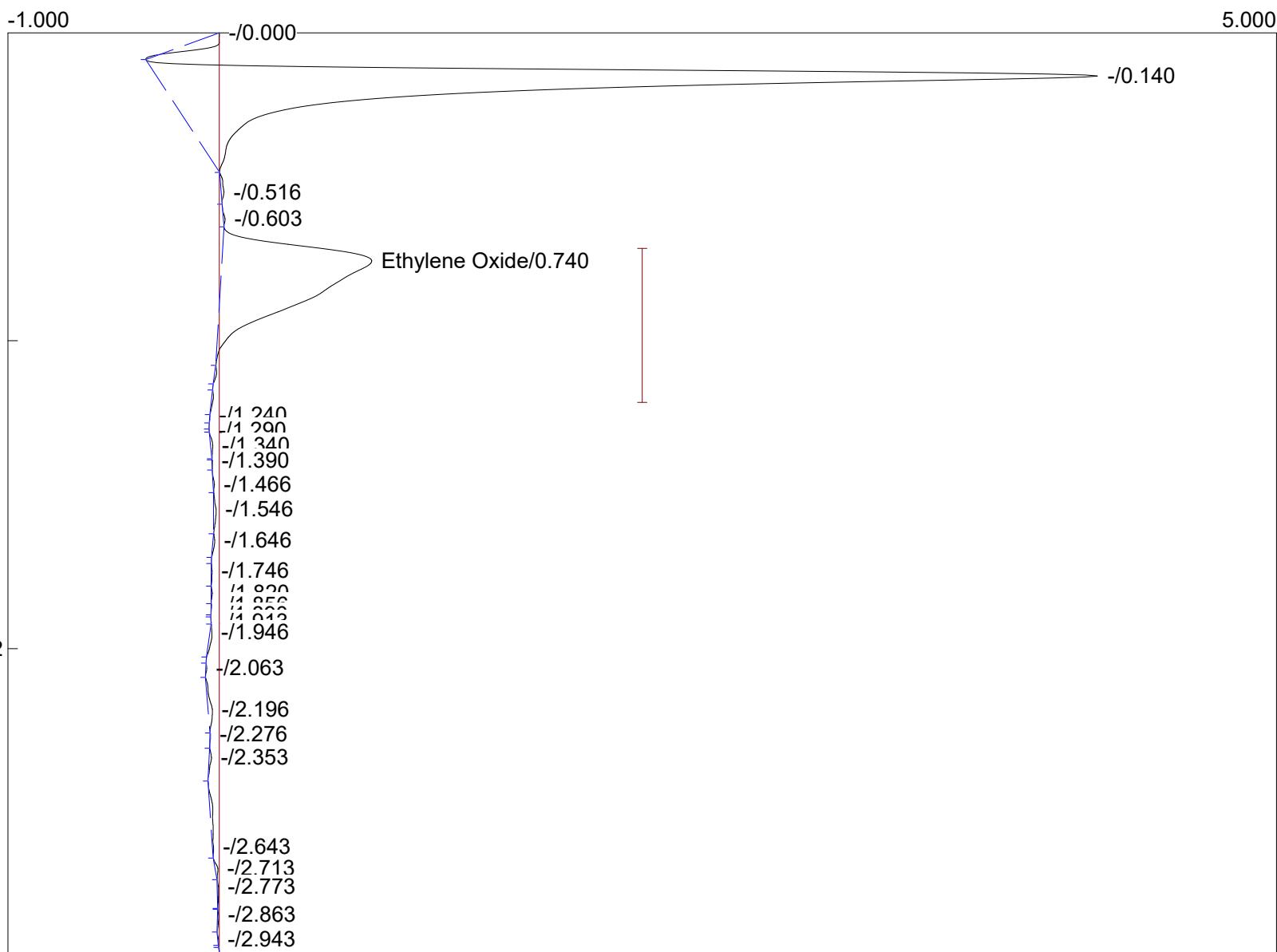
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_971..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 2



Component	Retention	Area
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Ethylene Oxide	0.740	3.1113
		3.1113

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 22:59:35

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

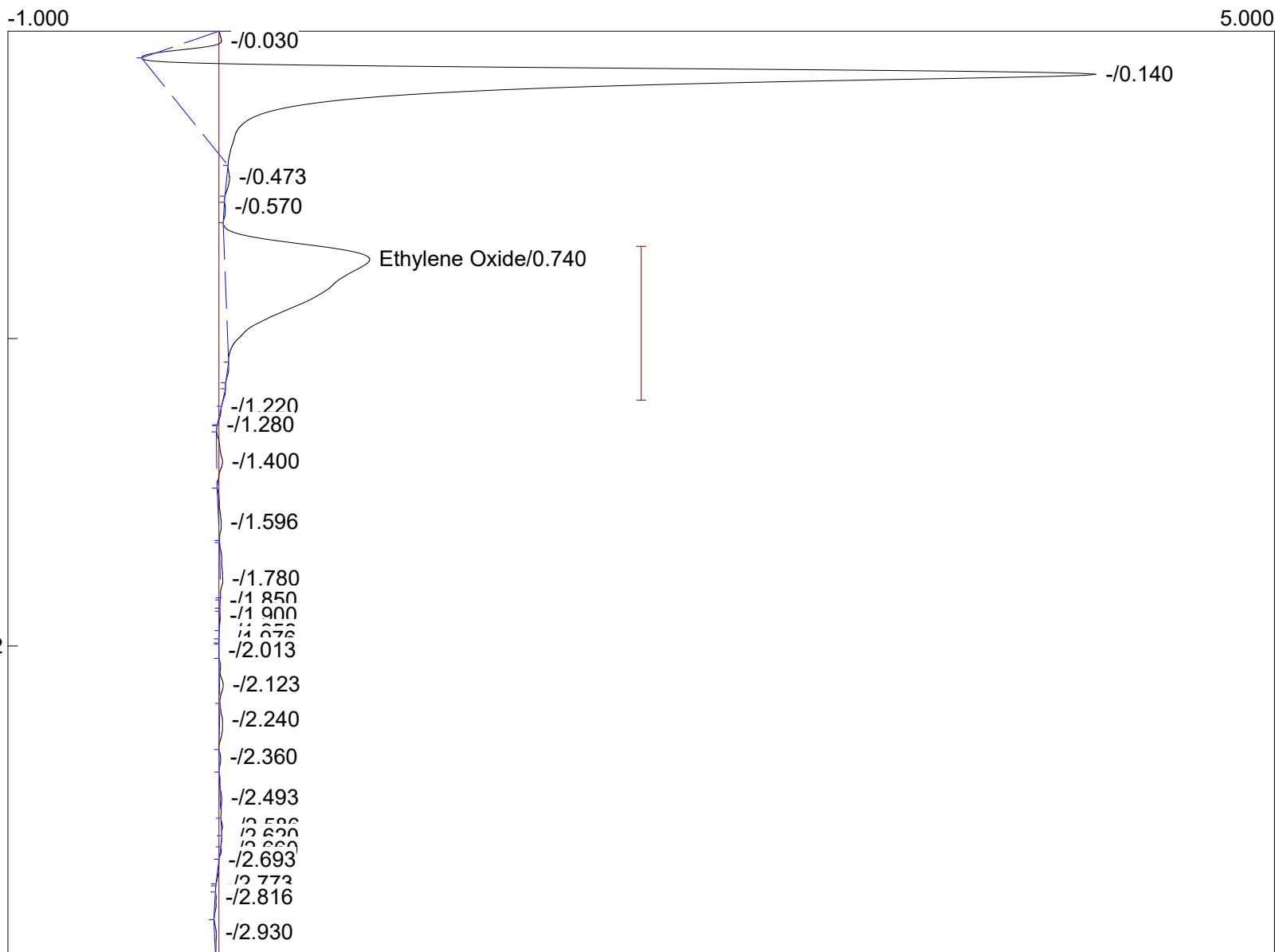
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_972..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 2



Component	Retention	Area
Ethylene Oxide	0.740	3.0844
		3.0844

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 23:03:35

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

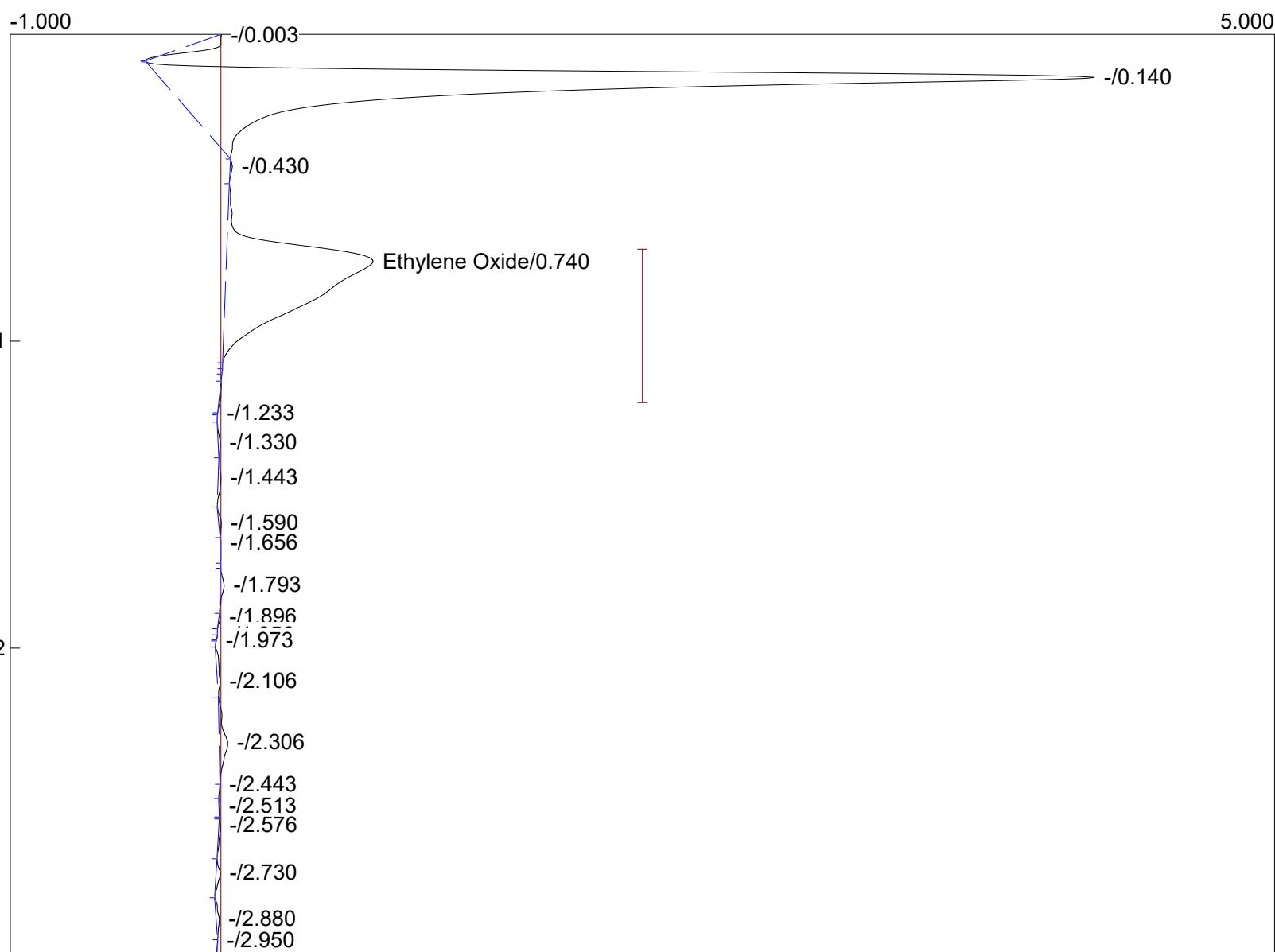
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_973..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 2



Component	Retention	Area
Ethylene Oxide	0.740	3.5334
		3.5334

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 23:07:35

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

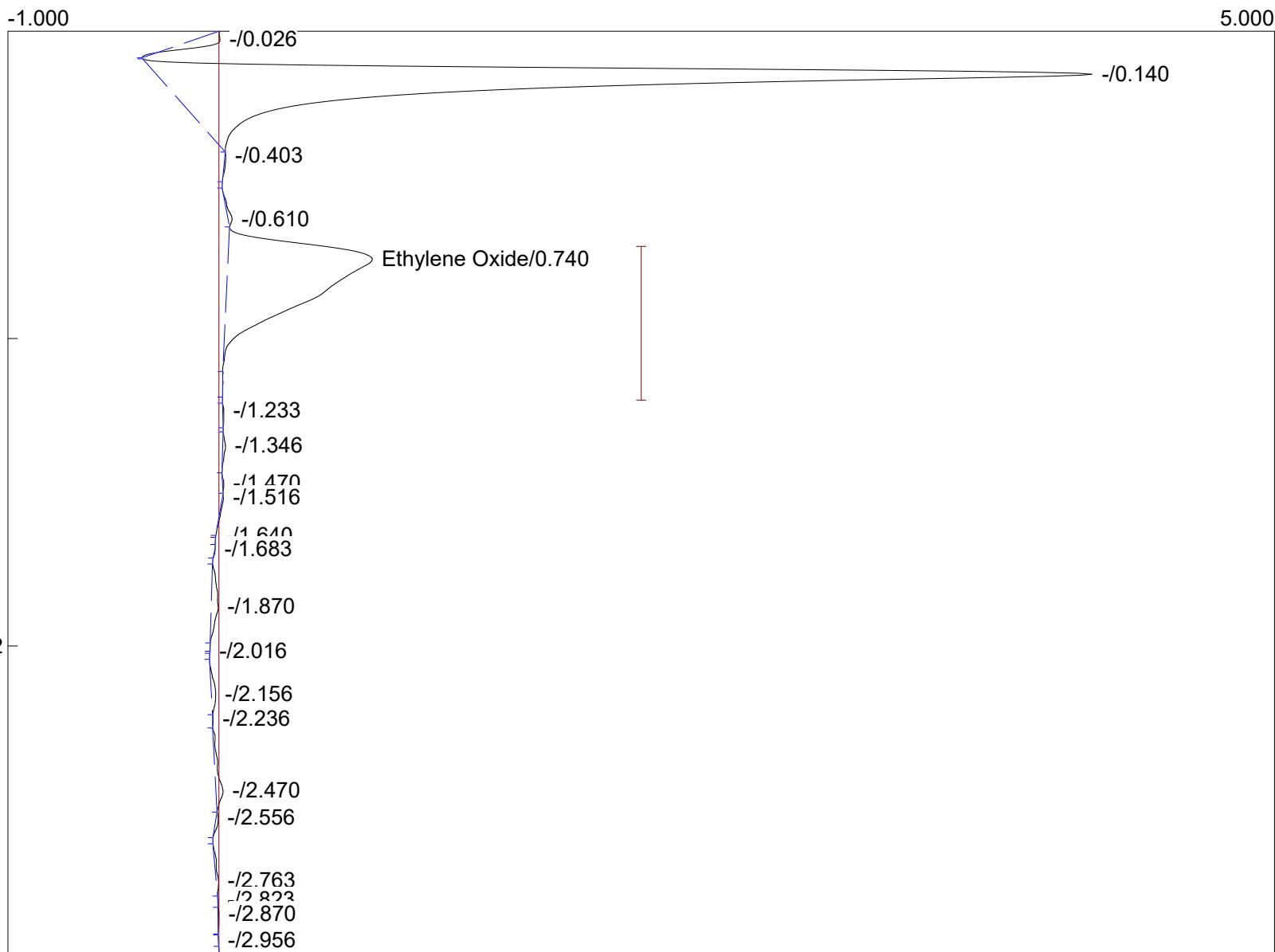
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_974..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 2



Component	Retention	Area
Ethylene Oxide	0.740	3.0760
		3.0760

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 23:11:35

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

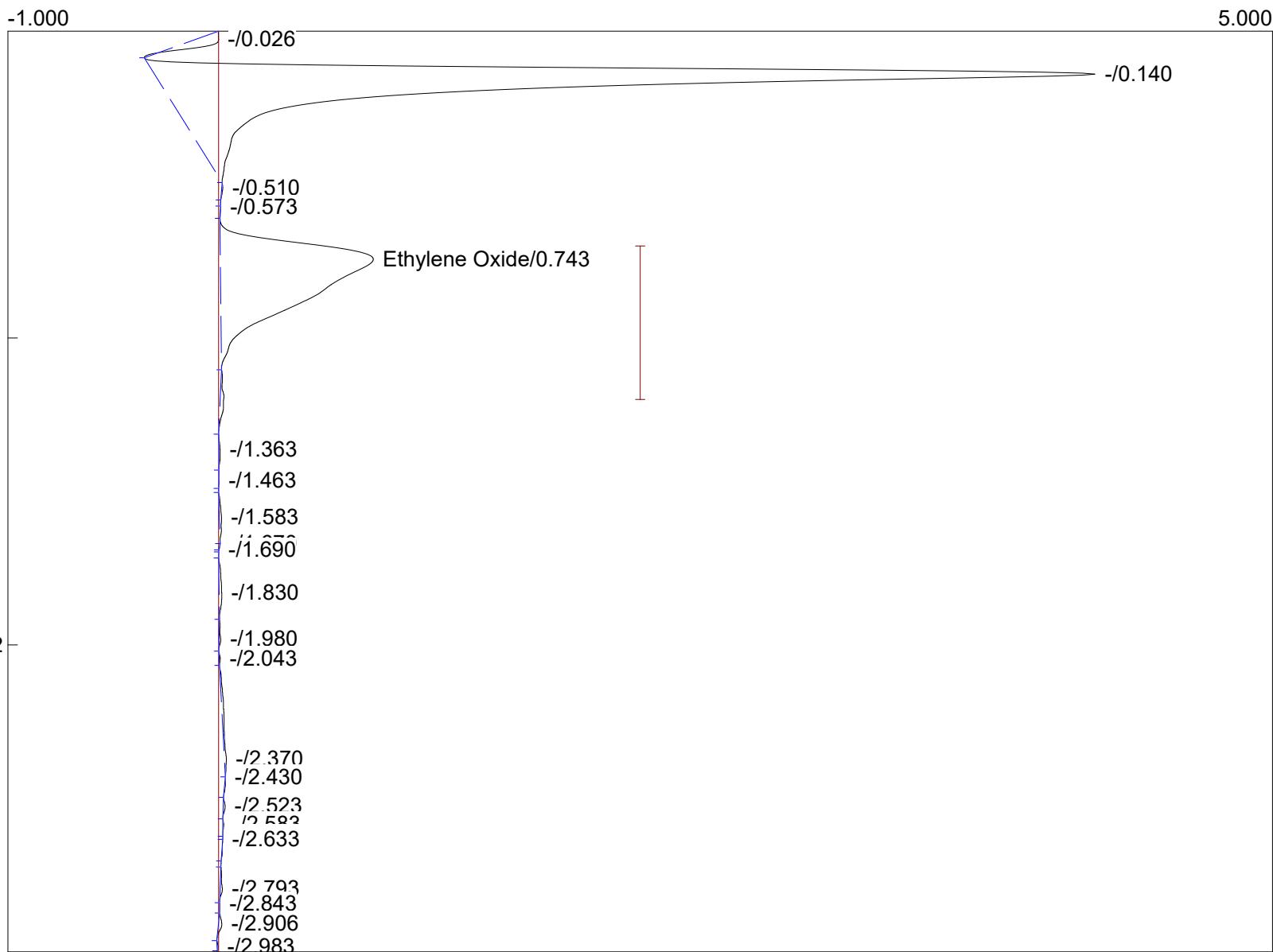
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_975..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 3



Component	Retention	Area
Ethylene Oxide	0.743	3.7324
		3.7324

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 23:15:35

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

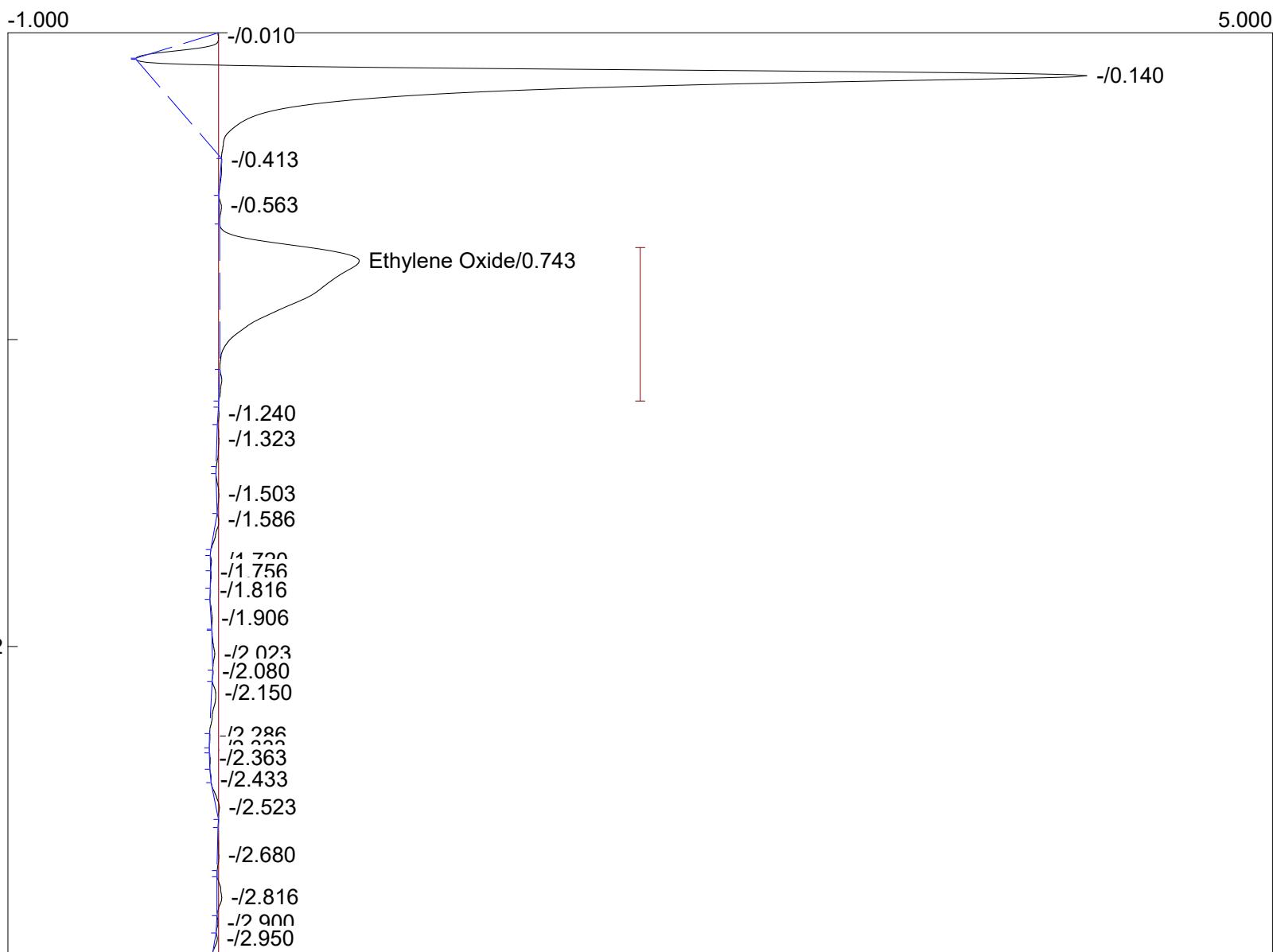
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_976..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 3



Component	Retention	Area
Ethylene Oxide	0.743	2.7842
		2.7842

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 23:19:35

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

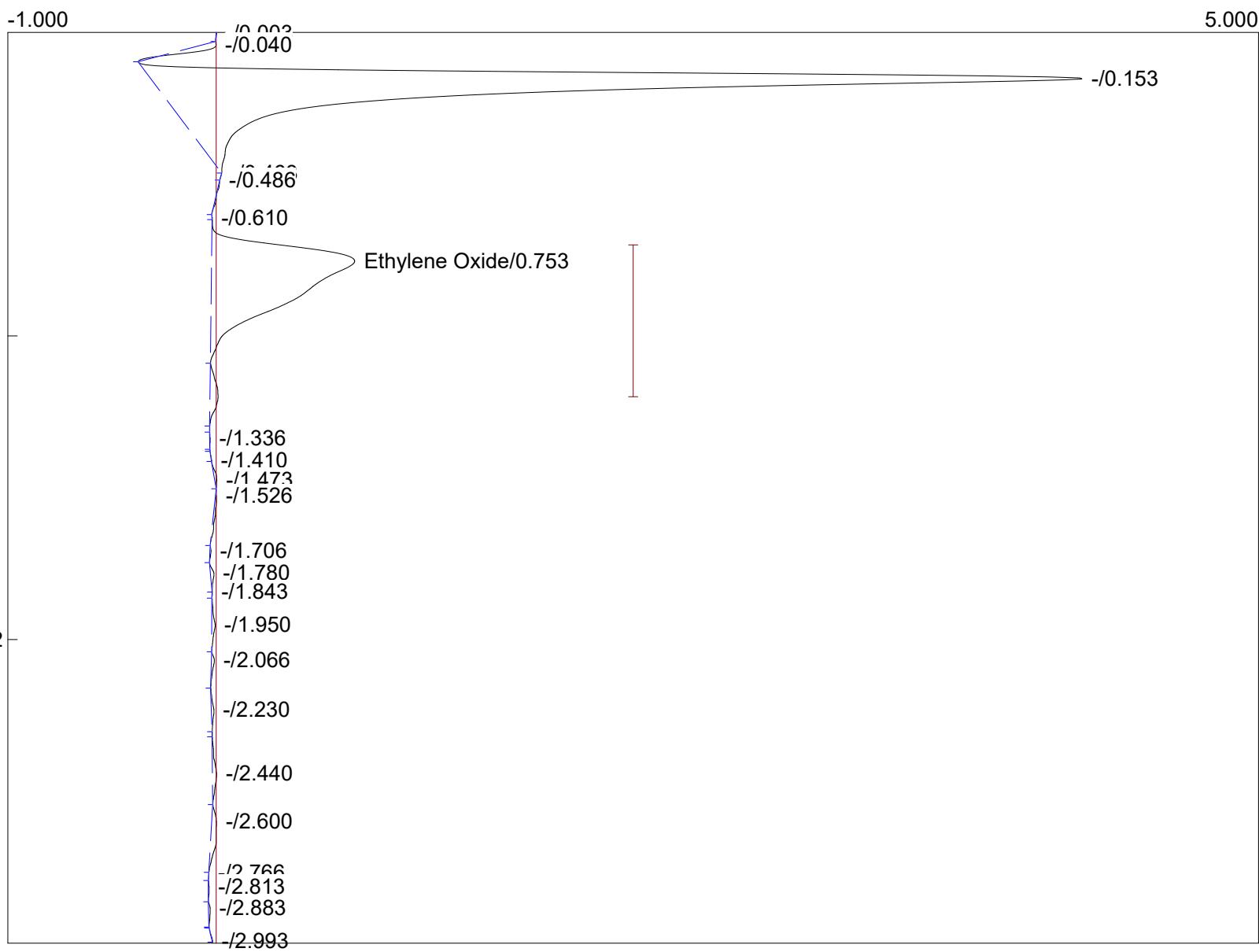
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_977..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 3



Component	Retention	Area
Ethylene Oxide	0.753	2.9044
		2.9044

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 23:23:35

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

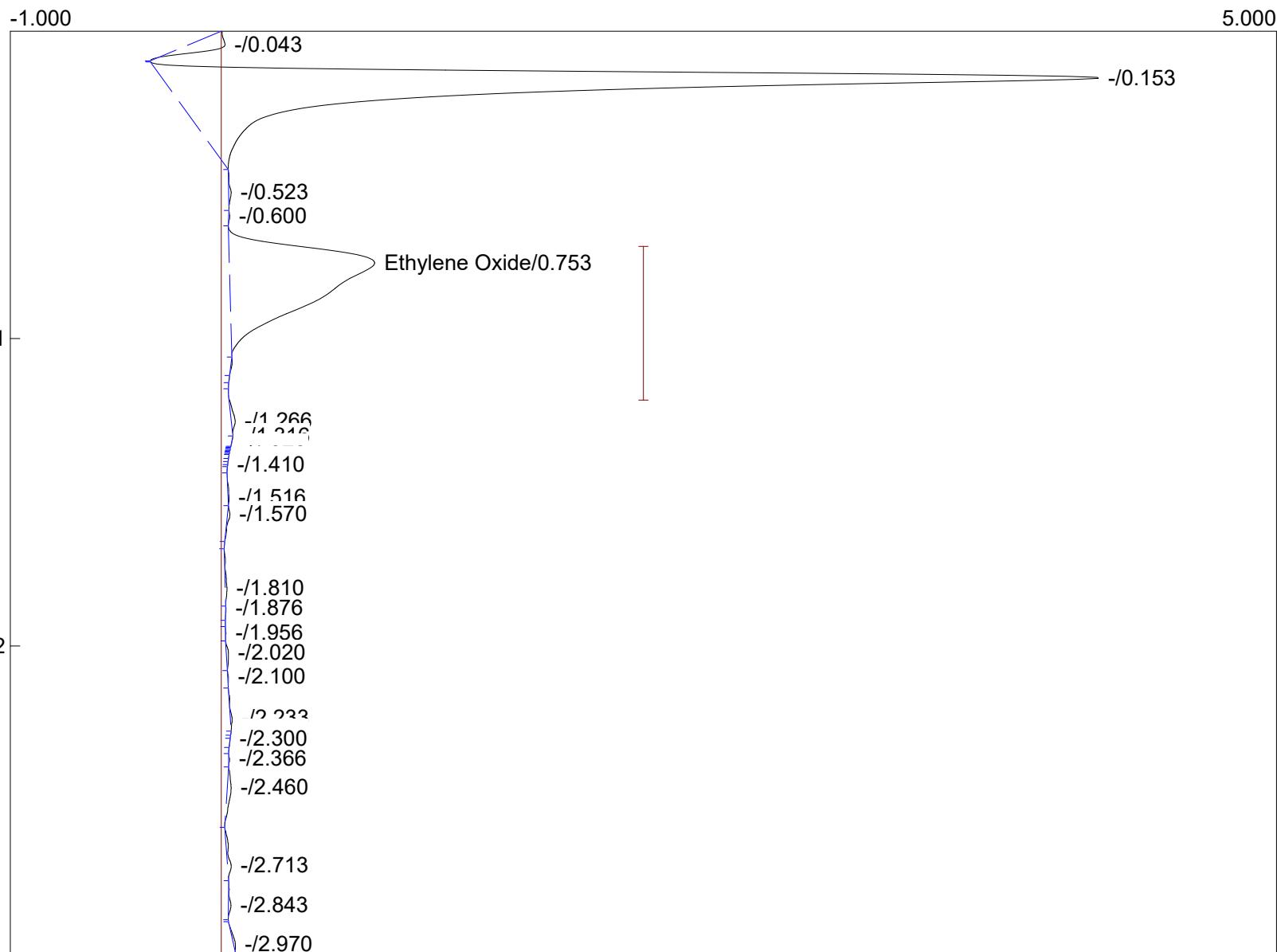
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_978..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 3



Component	Retention	Area
Ethylene Oxide	0.753	2.8986
		2.8986

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 23:27:36

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

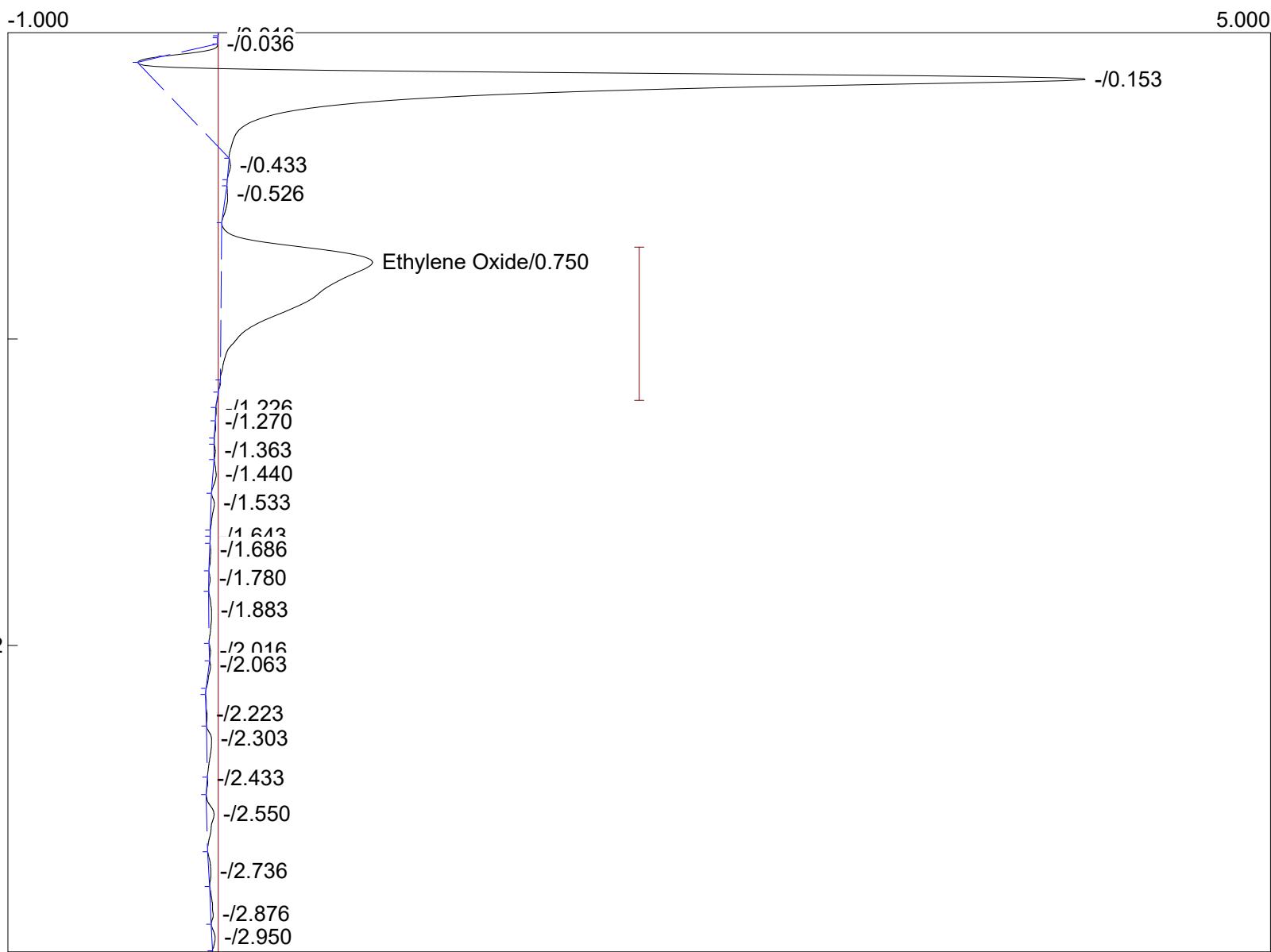
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_979..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 3



Component	Retention	Area
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Ethylene Oxide	0.750	3.4024
		3.4024

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 23:31:36

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

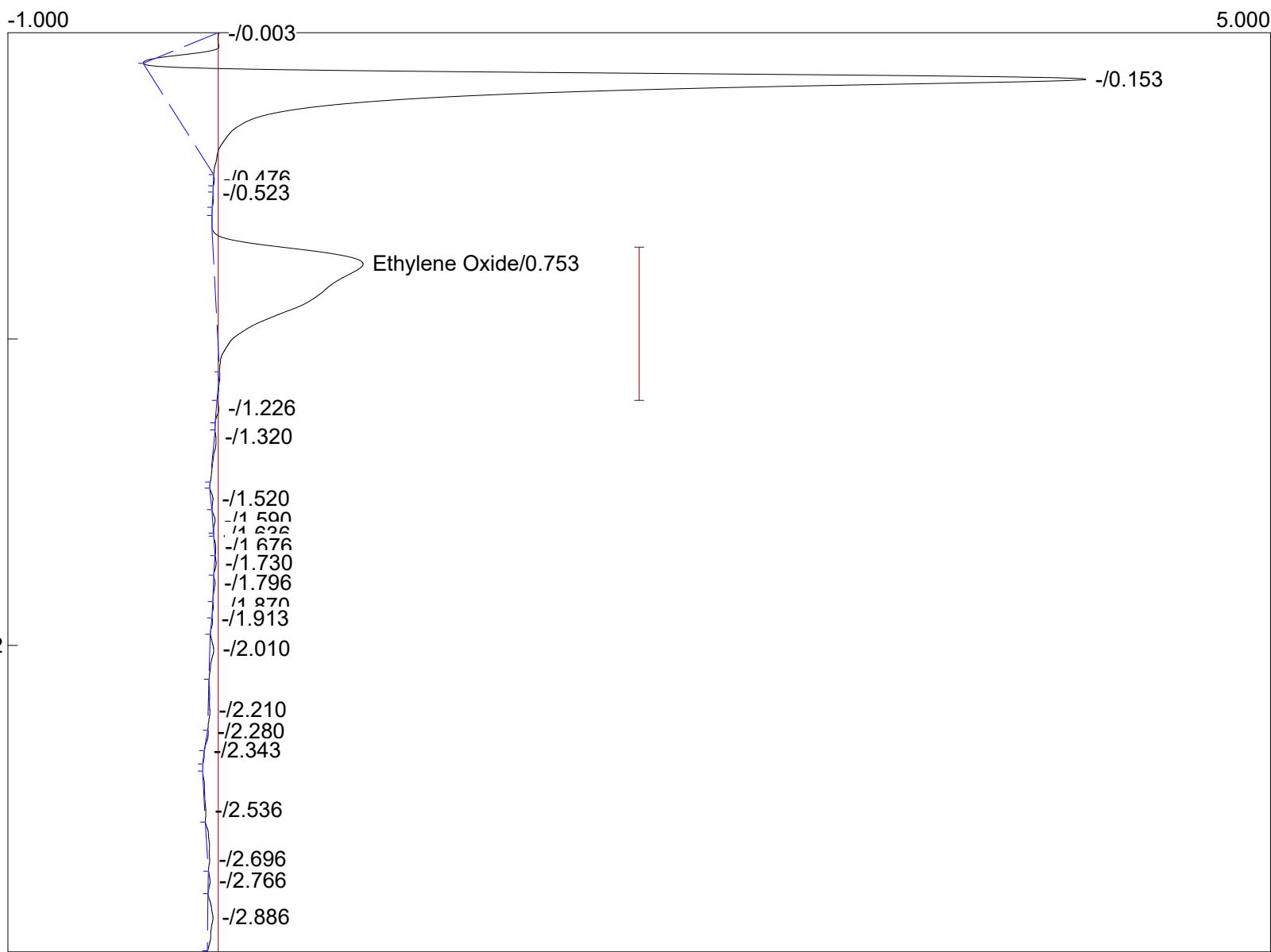
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_980..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 3



Component	Retention	Area
Ethylene Oxide	0.753	3.3888
		3.3888

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 23:35:36

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

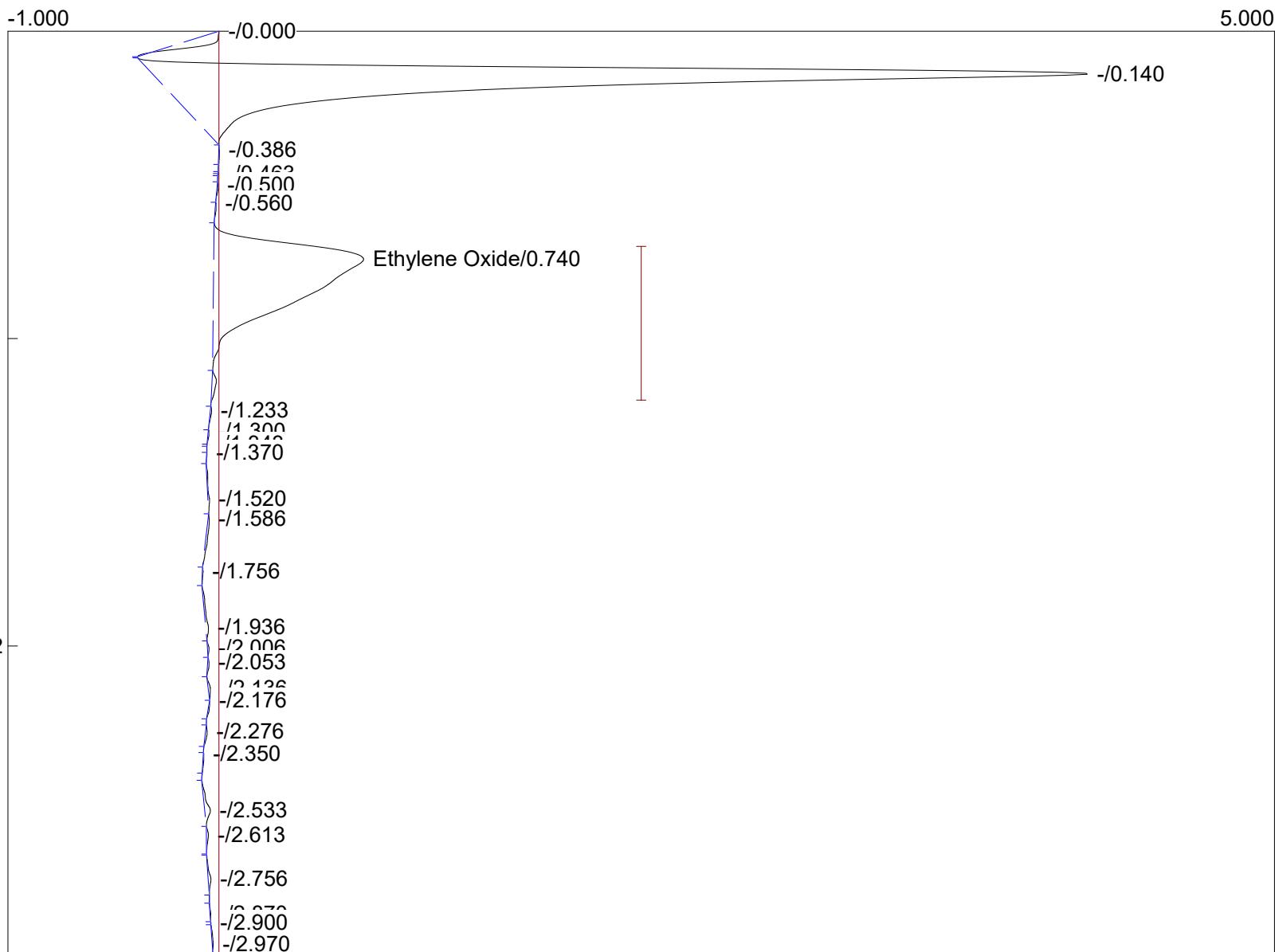
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_981..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 3



Component	Retention	Area
Ethylene Oxide	0.740	3.4320
		3.4320

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 23:39:36

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

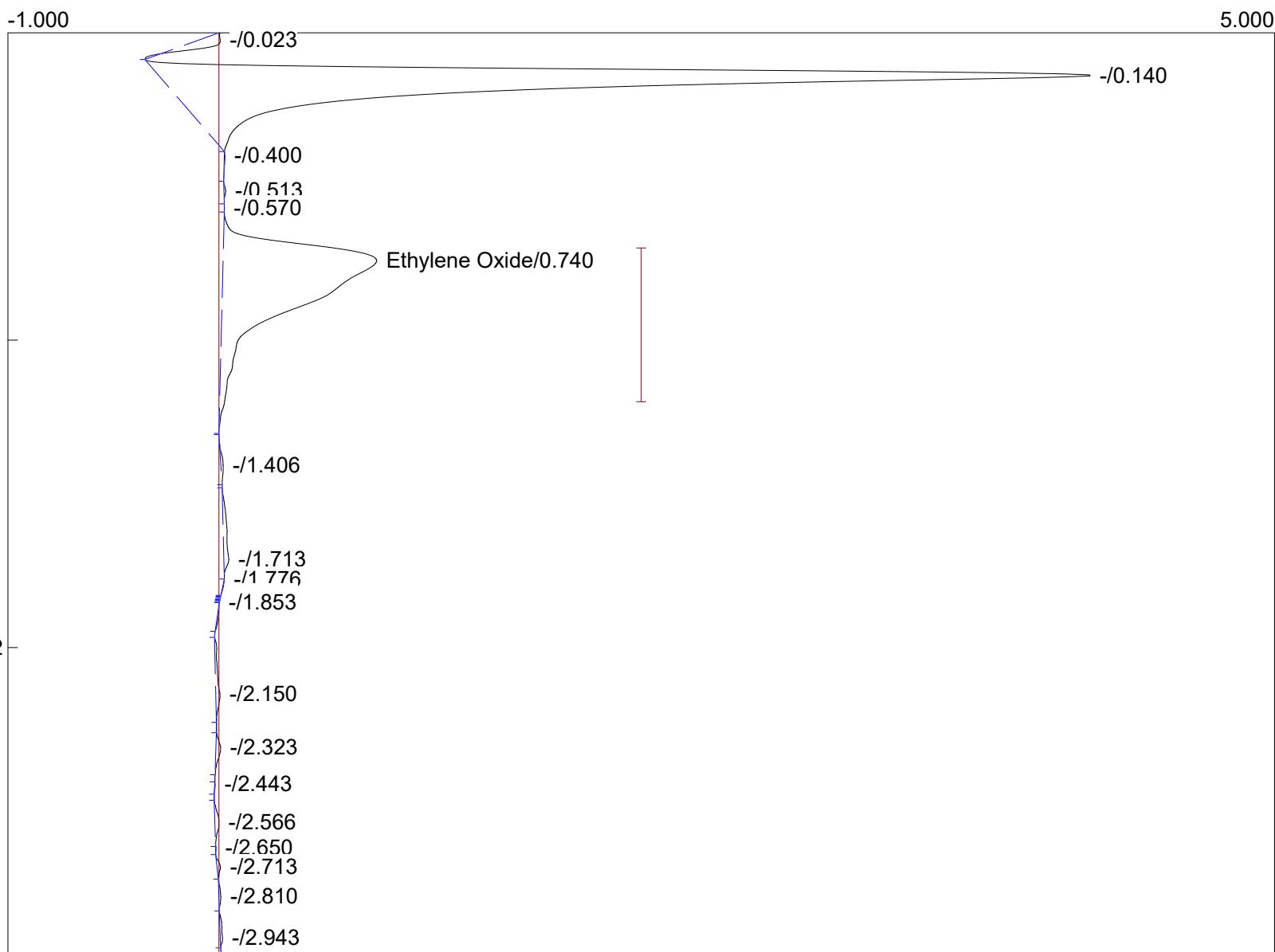
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_982..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 3



Component	Retention	Area
Ethylene Oxide	0.740	4.5250
		4.5250

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 23:43:36

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

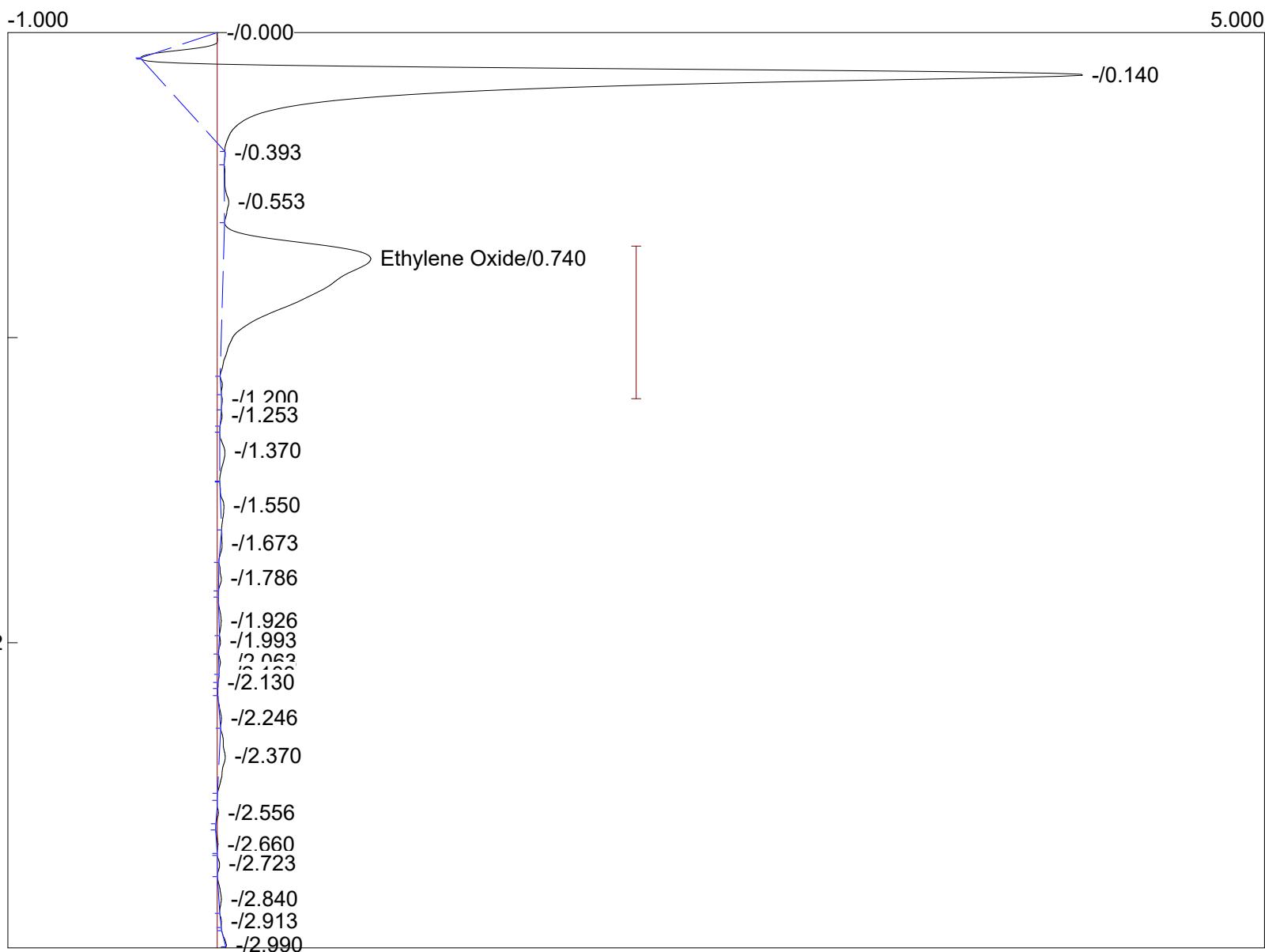
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_983..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 3



Component	Retention	Area
Ethylene Oxide	0.740	3.3899
		3.3899

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 23:47:36

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

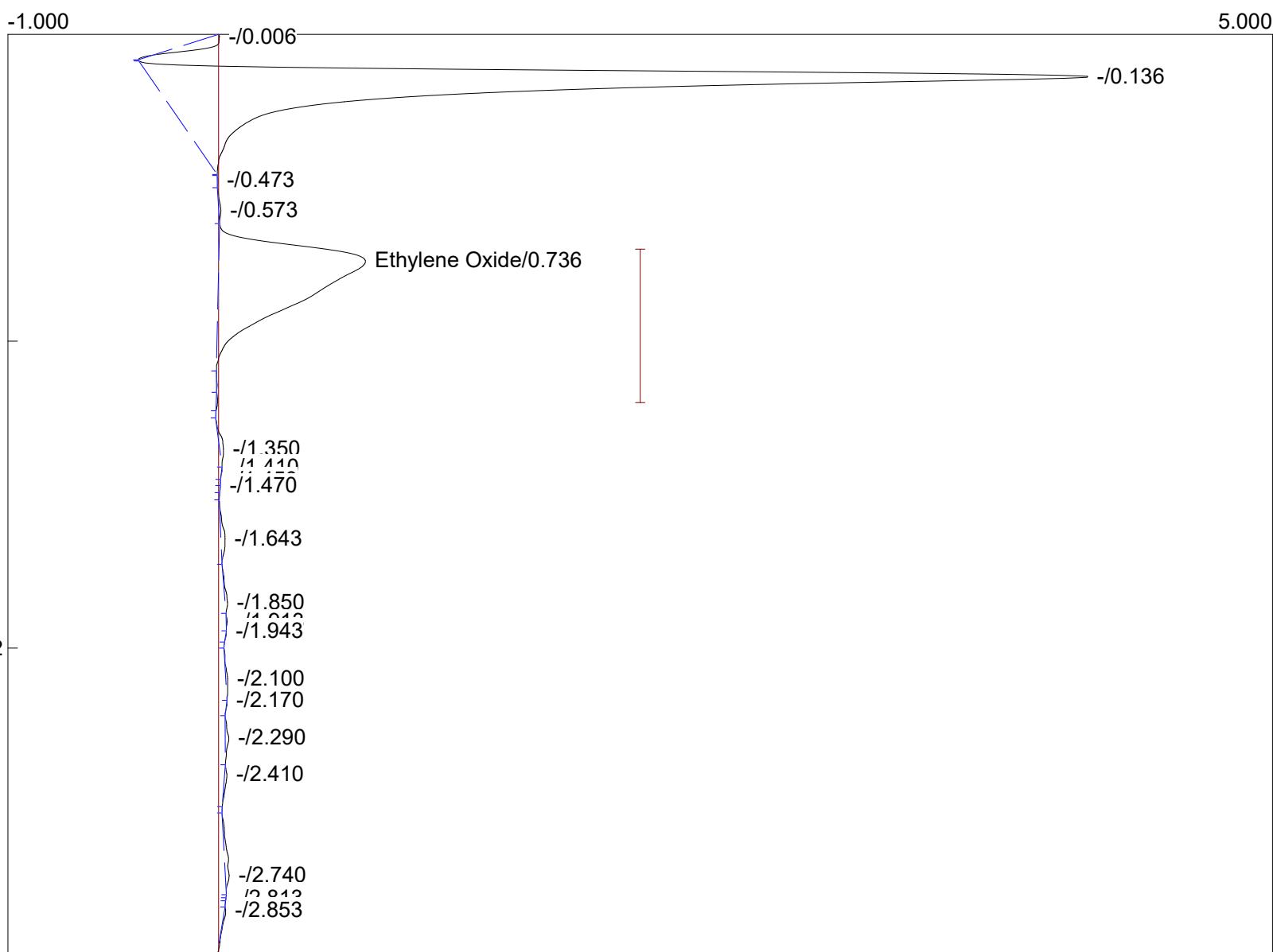
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_984..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 3



Component	Retention	Area
Ethylene Oxide	0.736	3.3160
		3.3160

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 23:51:36

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

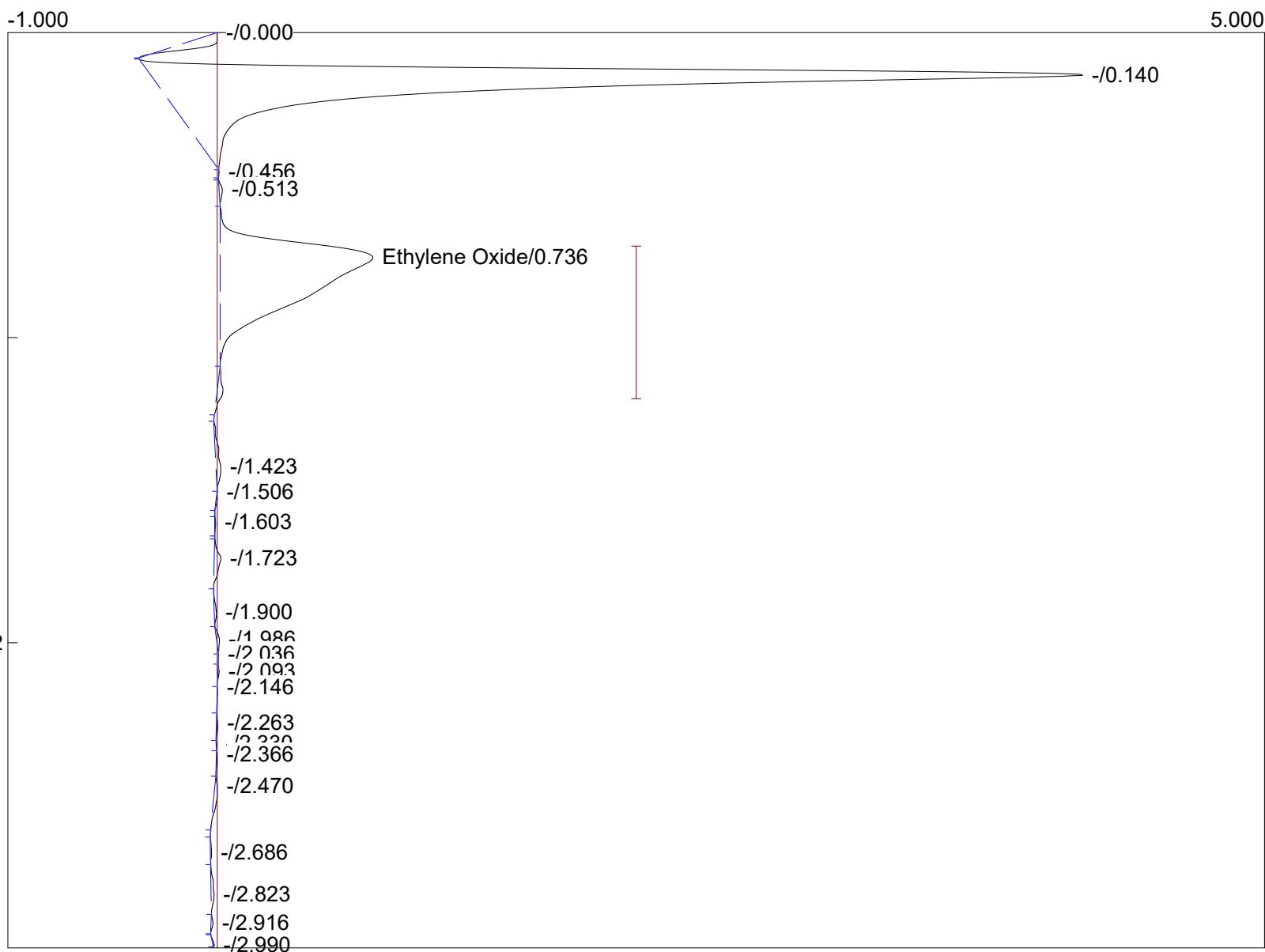
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_985..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 3



Component	Retention	Area
Ethylene Oxide	0.736	3.4900
		3.4900

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 23:55:36

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

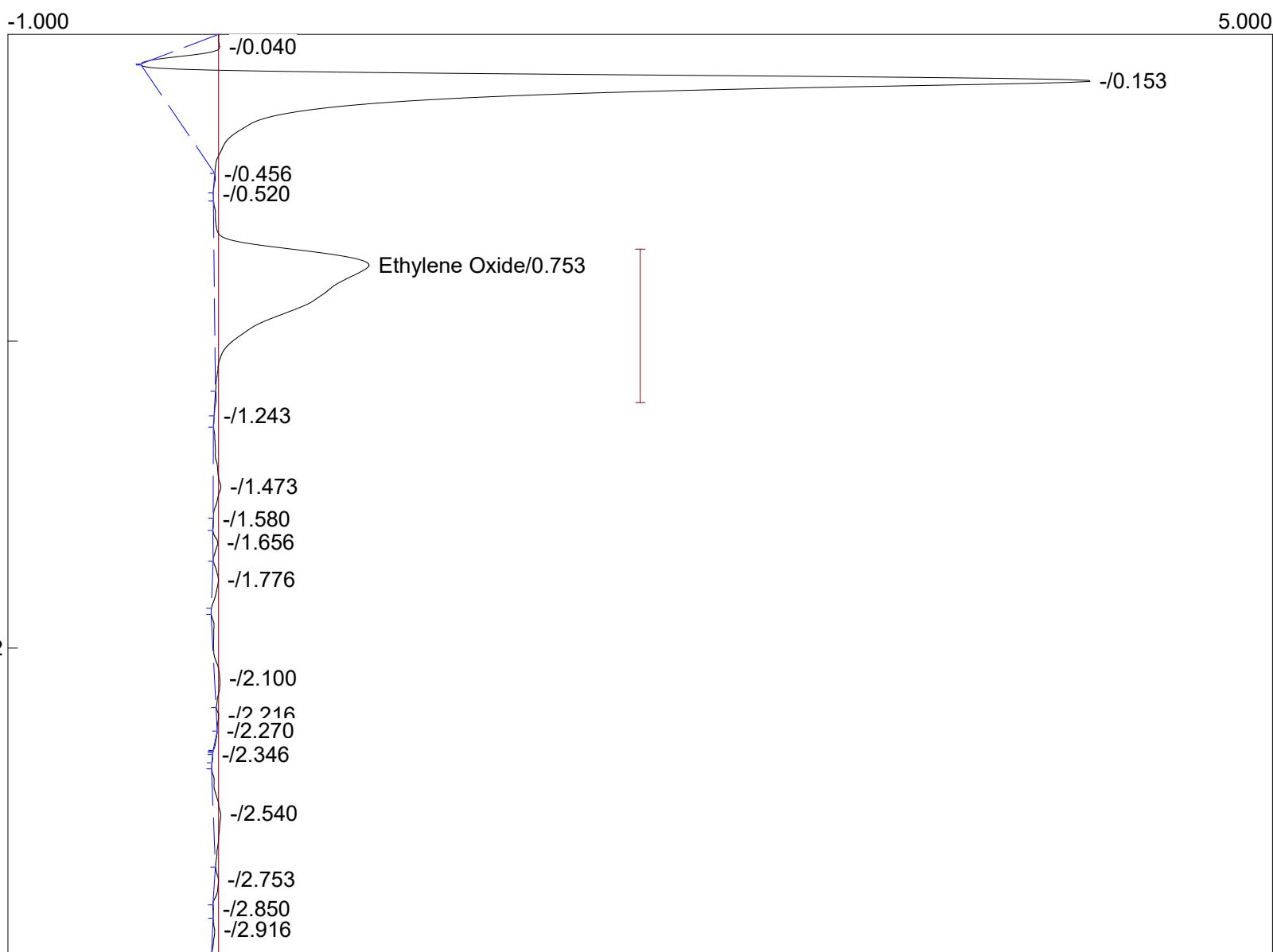
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_986..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 3



Component	Retention	Area
Ethylene Oxide	0.753	3.8158
		3.8158

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/09/2020 23:59:36

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

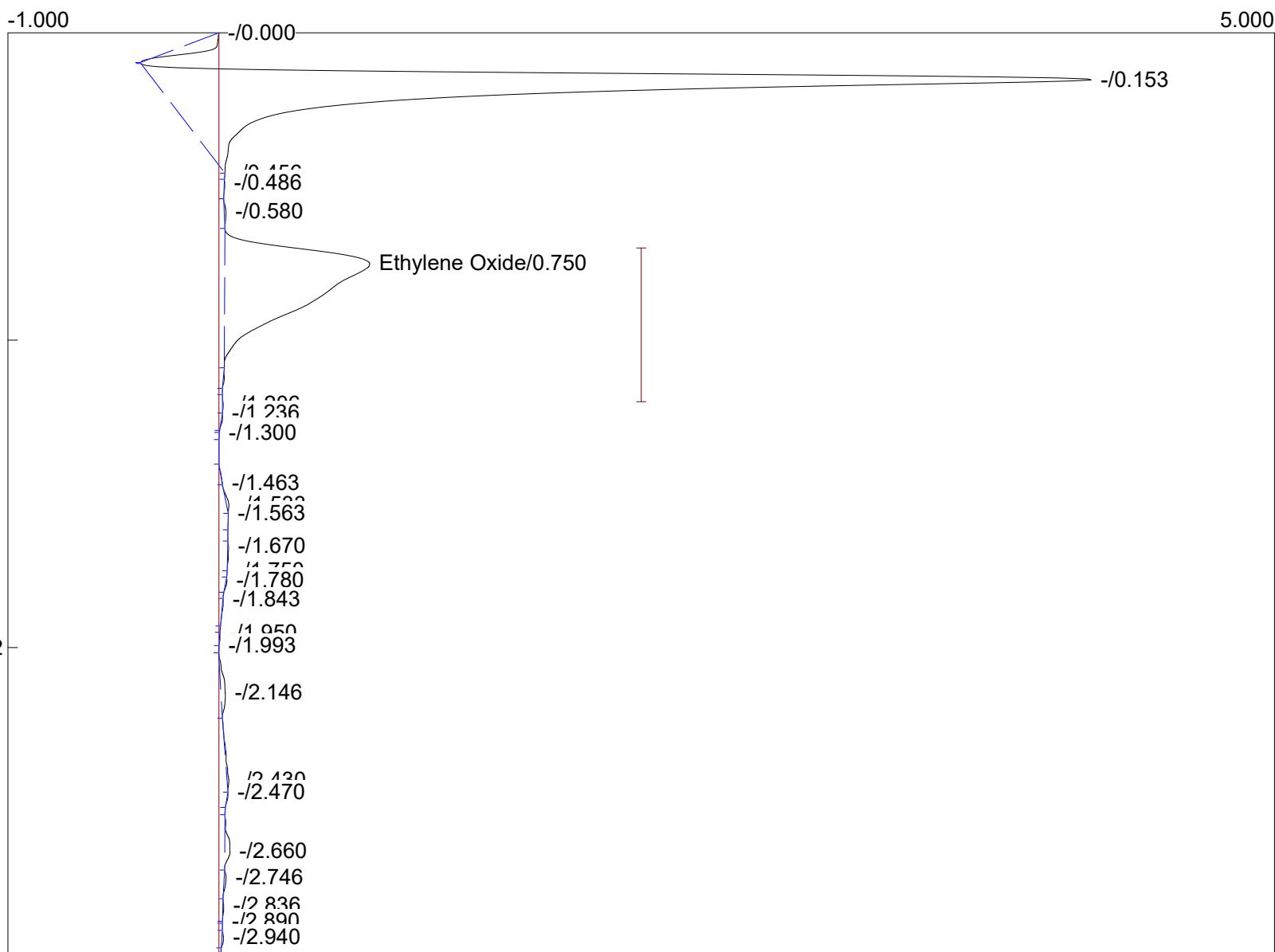
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_987..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 3



Component	Retention	Area
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Ethylene Oxide	0.750	3.0318
		3.0318

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/10/2020 00:03:36

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

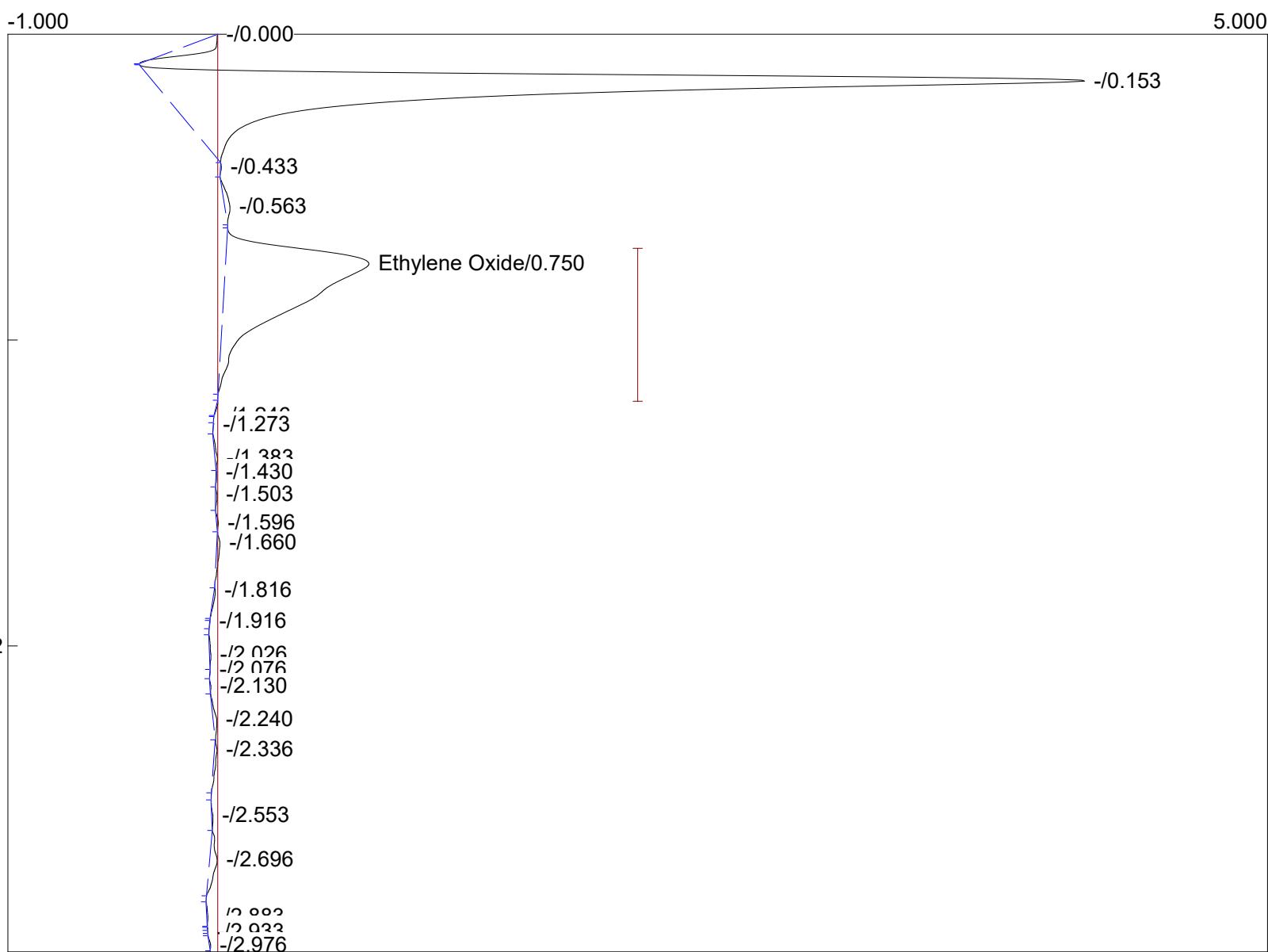
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_988..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 3



Component	Retention	Area
Ethylene Oxide	0.750	3.1634
		3.1634

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/10/2020 00:07:36

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

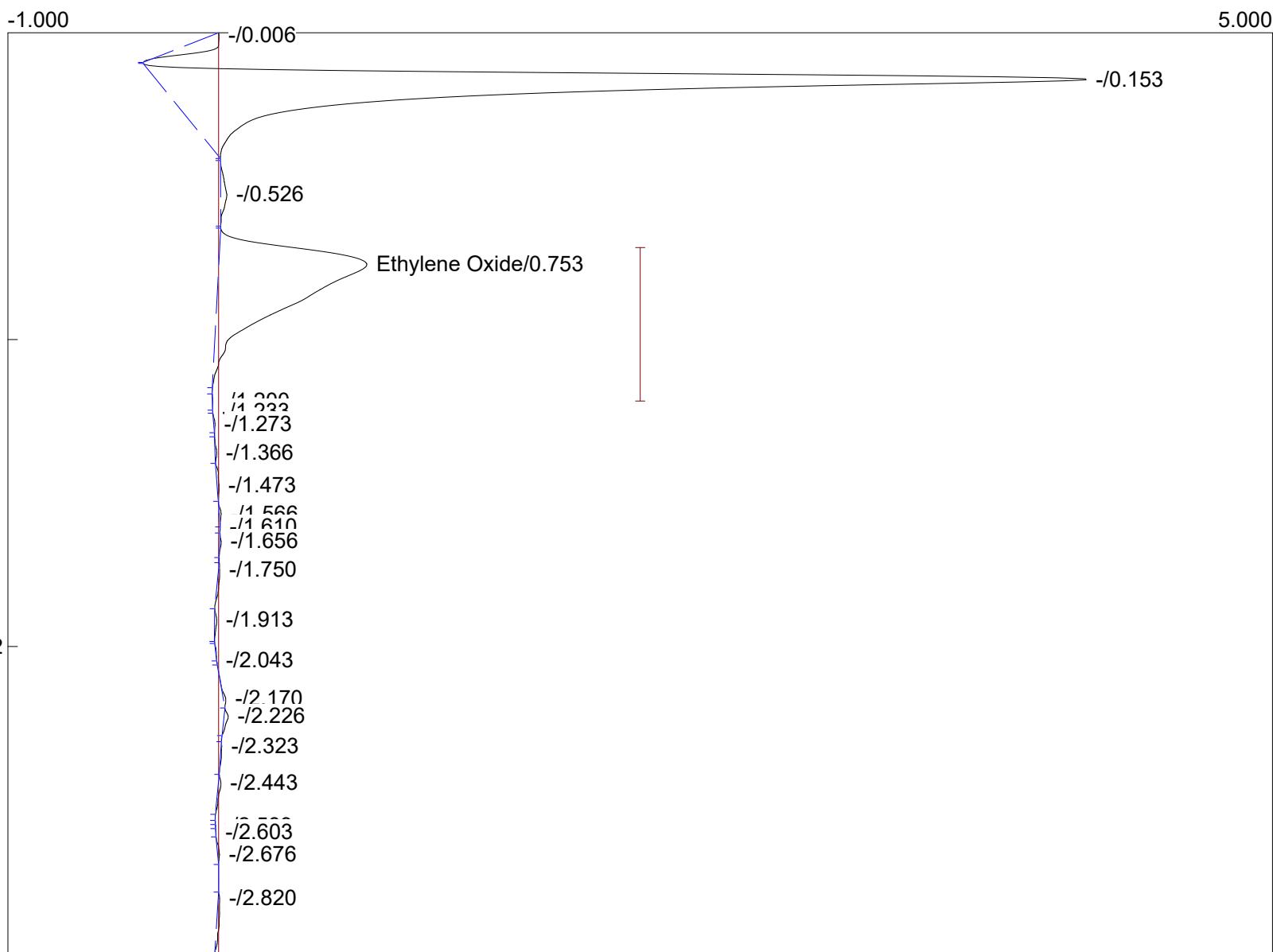
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_989..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 3



Component	Retention	Area
Ethylene Oxide	0.753	3.1552
		3.1552

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/10/2020 00:11:36

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

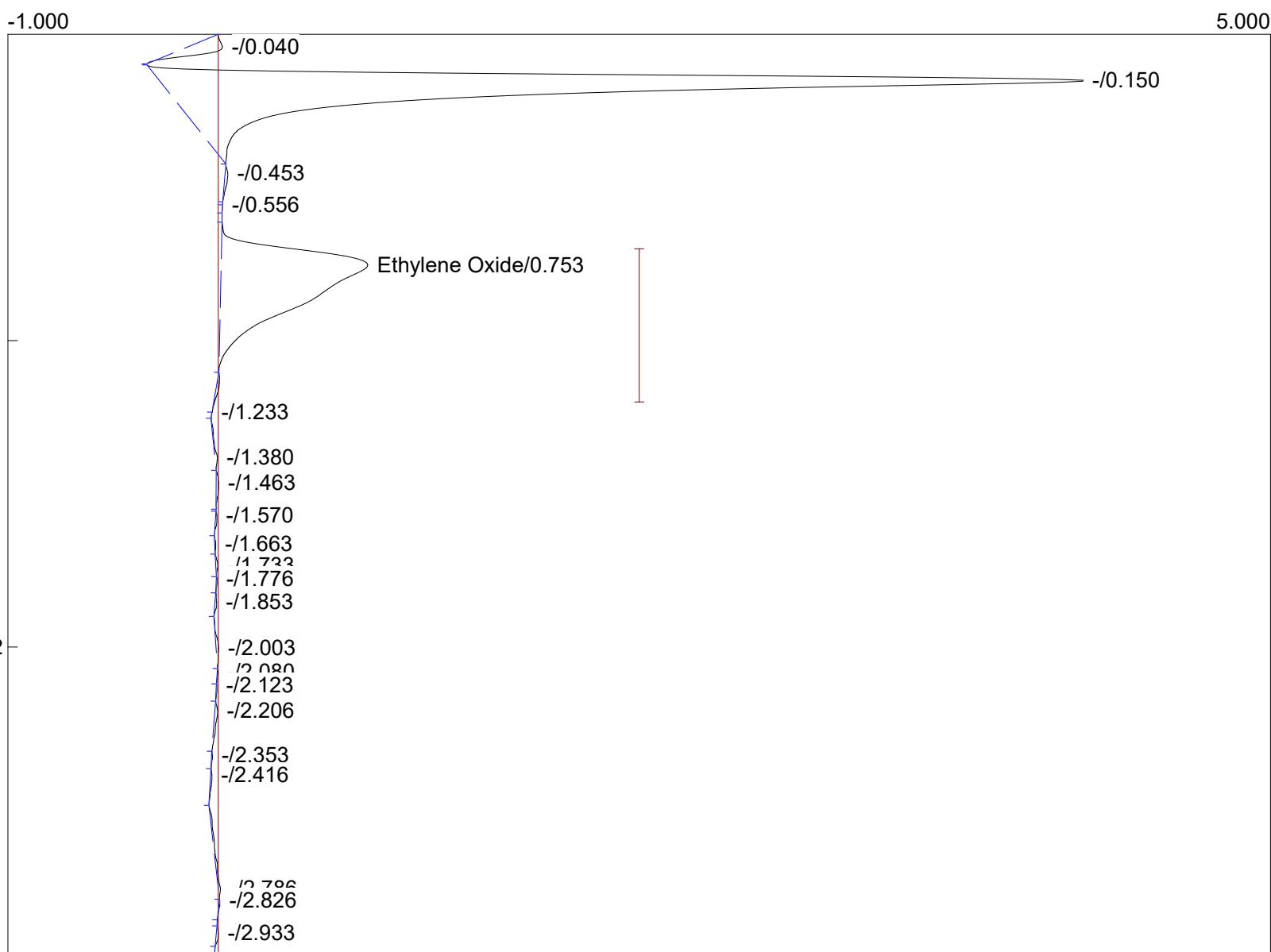
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_990..CHR ()

Sample: Sample

Operator: L Christopher Heilner

Comments: Aeration Room Vent Run 3



Component	Retention	Area
Ethylene Oxide	0.753	3.0843
		3.0843

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/10/2020 15:28:13

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_1220.()

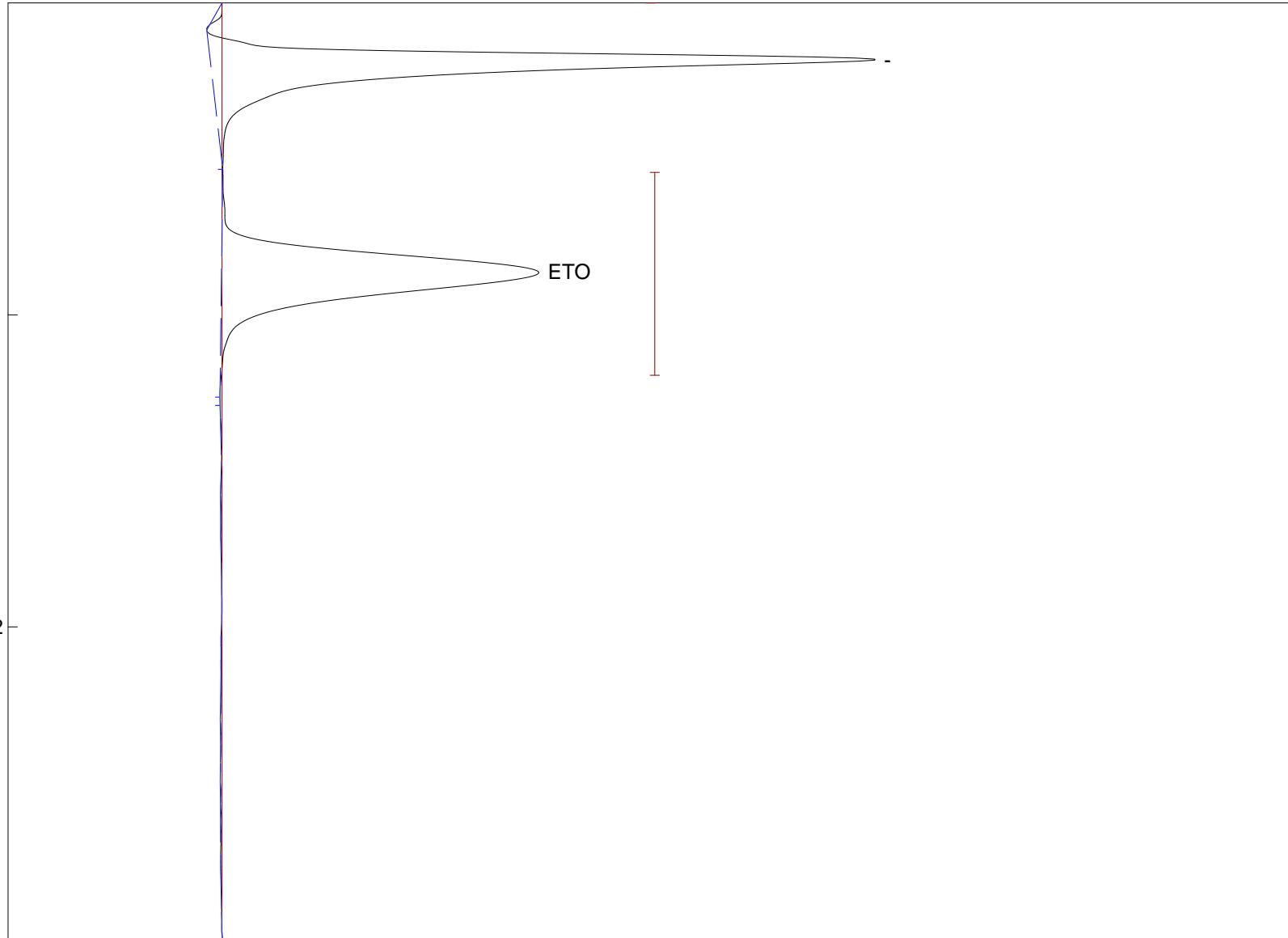
Sample: Sample

Operator: L Christopher Heilner

Comments: 10 ppm Cal Gas Post Run Drift

-3.904

19.536



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.863	56.3422
1			56.3422

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/10/2020 15:31:19

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

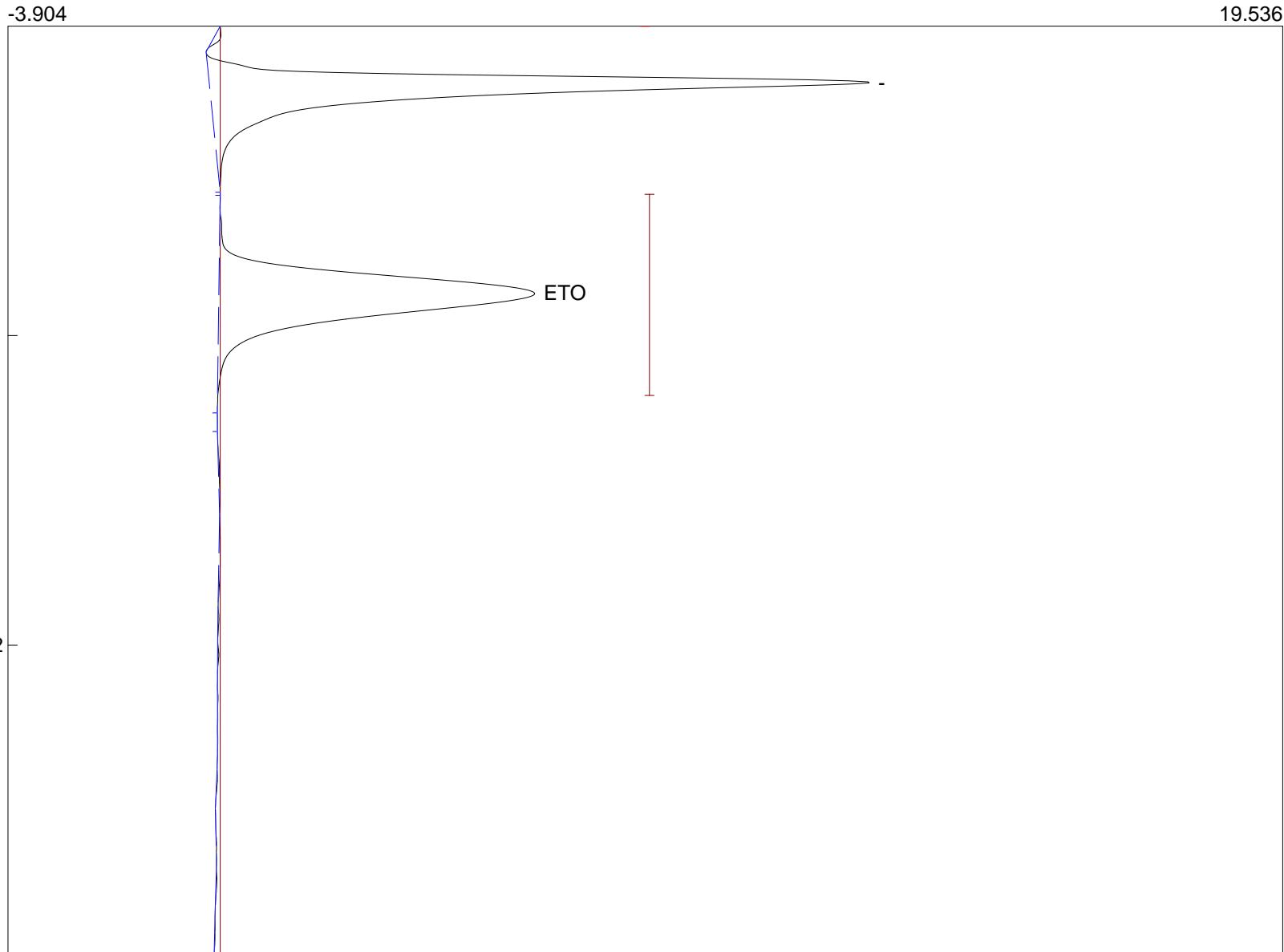
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_1221.()

Sample: Sample

Operator: L Christopher Heilner

Comments: 10 ppm Cal Gas Post Run Drift



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.863	56.7828
1			56.7828

Lab name: LCH Consulting Associates, LLC

Client: Customed, Inc.

Client ID: CI

Analysis date: 01/10/2020 15:34:25

Method: USEPA Method 18

Lab ID: PADEP 15-05860

Description: FID

Column: Haysep D

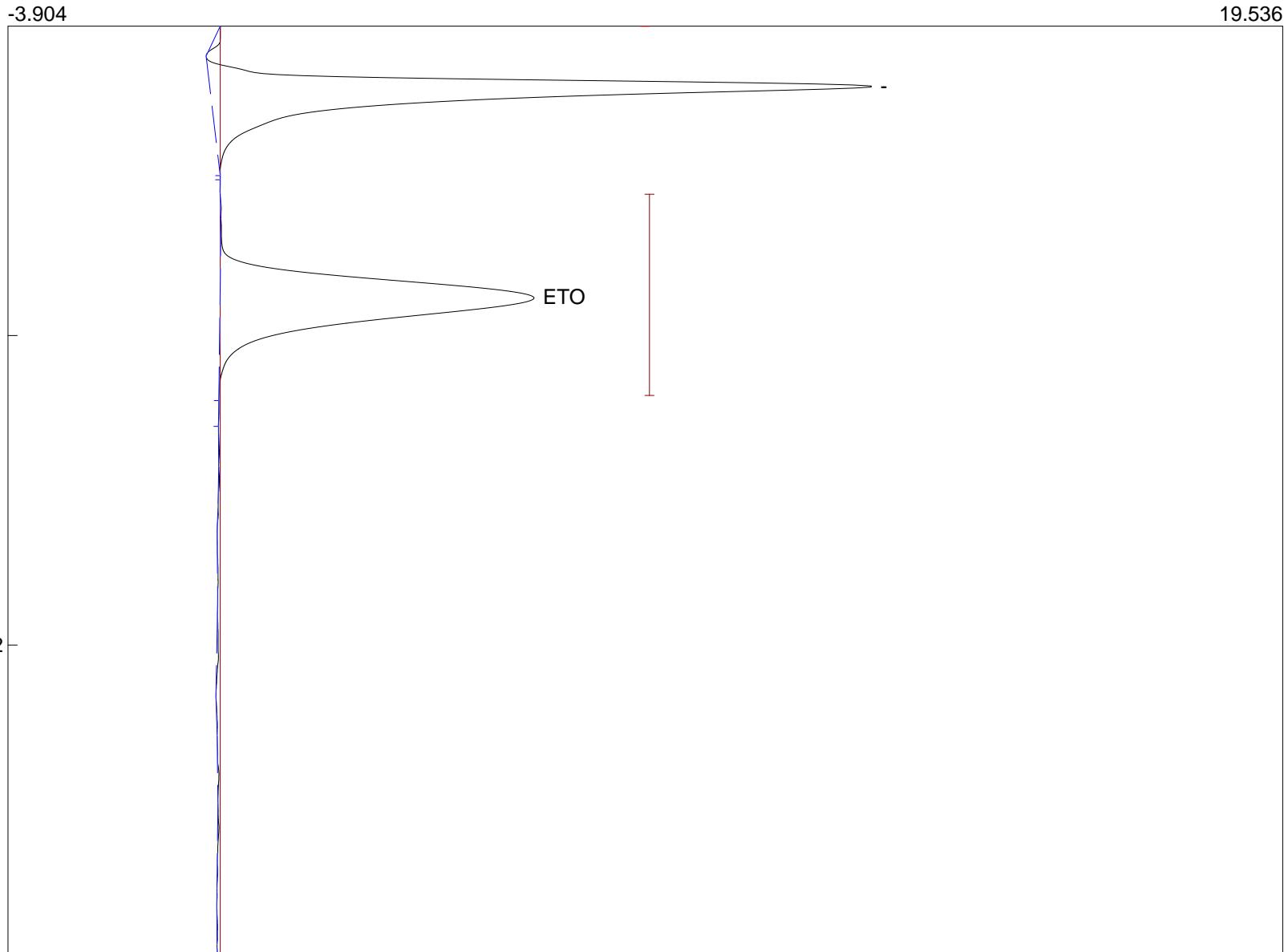
Carrier: UHP 99.99999% Helium AT 18 PSI

Data file: Customed2019_Q4_1222.()

Sample: Sample

Operator: L Christopher Heilner

Comments: 10 ppm Cal Gas Post Run Drift



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.876	49.7302
1			49.7302

ATTACHMENT E

SUBPART O CALCULATIONS

Run 1	Thursday, January 9, 2020			Chamber Temperatures and Pressure with Units		
		units	1	1		
Chamber Number						
Run ID		Empty Chamber	Test			
Chamber Volume	V	cubic feet	1212.816			
Standard Molar Volume	SV	cubic feet	385.32			
Mol. Wt. EO	MWEO	# / # mole	44.05			
Mol. Wt.H2O	MWH2O	# / # mole	18			
Mol. Wt. N2	MWN2	# / # mole	28			
Standard Temperature	Tstd	degree R	528			
Standard Barometric Pressure	Pstd	inch Hg	29.92			
Barometric Pressure	Pbar	inch Hg	30.0			
Conversion factor millibars to inches Hg			0.0295			
Conversion factor kg to pounds			2.2046			
Chamber pressure after nitrogen wash		mbar	237.2881356	7.0		
Chamber pressure after nitrogen wash		inch Hg	7.00	F	F	
Chamber temperature after nitrogen wash		degree C	54.4	132.0	128.0	130.0
Chamber temperature after nitrogen wash		degree R	590.0			
Volume nitrogen in chamber		cubic feet	316.22			
Pound moles nitrogen in chamber			0.91			
Mass nitrogen in chamber		pounds	25.61			
Chamber pressure after humidification	P	mbar	271.1864407	8.0		
Chamber pressure after humidification	P	inch Hg	8.00			
Pressure increase due to humidification	P	inch Hg	1.00	F	F	
Chamber temperature after humidification		degree C	53.3	128.0	128.0	128.0
Chamber temperature after humidification		degree R	588.0			
Volume H2O in chamber		cubic feet	45.02			
Pound Moles of H2O at chamber pressure			0.12			
Mass H2O at chamber pressure		pounds	2.10			
Mass EtO charged to chamber		kg	20	43.00		
Mass EtO charged to chamber	Wc	pounds	43.0			
Chamber pressure after EtO injection		mbar	661.0169492	19.5		
Chamber pressure after EtO injection		inch Hg	19.50	F	F	
Chamber Temperature after EtO injection		degree C	55.3	132.0	131.0	131.5
Chamber Temperature after EtO injection		degree R	591.5			
Chamber temperature after nitrogen blanket		degree R	591.5			
Total Moles N2 in chamber			0.91			
Total mass nitrogen in chamber		pounds	25.61			
Total volume gas in chamber		std. cubic feet	705.58			
Pound Moles EtO injected			0.98			
Weight % N2	WN2	%	36.22%			
Weight % water	WH2O	%	2.97%			
Weight % EtO	WE0	%	60.81%			
EtO mole fraction	%EOv	%	48.62%			
H2O mole fraction	%H2Ov	%	5.82%			
N2 mole fraction	%N2v	%	47.18%			
Chamber pressure after evacuation		mbar	237.2881356	7.0		
Chamber pressure after evacuation		inch Hg	7	F	F	
Chamber temperature after 1st evacuation		degree C	53.6	130.0	127.0	128.5
Chamber temperature after 1st evacuation		degree R	588.5			
Total volume gas in chamber		std. cubic feet	254.58			
Percent chamber gas evacuated		%	63.92%			
Residual Mass EtO remaining in chamber	Wr	pounds	15.51			
Mass EtO at Inlet to scrubber	Wi	pounds	27.49			
Concentration EtO in Scrubber Outlet	C	ppm	12.5			
Volume gas exiting scrubber	V	dscf	205.0			
Mass EtO exiting scrubber	Wb	pounds	0.00029			
Control Device Efficiency	% Eff	%	99.99894%			

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Customed, Fajardo, Puerto Rico				
Run No.	One	Date	Thursday, January 9, 2020	
Barometric Pressure	30	in Hg	Moisture %	7.95%
Stack (Static) Pressure	0.15	in H ₂ O	mol wt stack gas Md	30.00
Diameter of Stack	4	inch	mol wt stack gas Ms	29.05
Elapsed Time (Minutes)	Stack Differential Pressure ("H ₂ O)	Stack Gas Temperature (°F)	Stack Gas Velocity (FPS)	Stack Gas Volumetric Flow (DSCF)
858	0.010	86.0	6.70	31.30
859	0.005	89.0	4.75	22.07
900	0.005	95.0	4.78	21.95
901	0.005	102.0	4.81	21.81
902	0.005	108.0	4.83	21.70
903	0.005	116.0	4.86	21.55
904	0.005	118.0	4.87	21.51
905	0.005	114.0	4.86	21.58
906	0.005	116.0	4.86	21.55
Total				205.02
Average				107.3

Run 2	Thursday, January 9, 2020			Chamber Temperatures and Pressure with Units
Chamber Number		units	1	1
Run ID	SL20008		Test	min max avg
Chamber Volume	V	cubic feet	1212.816	
Standard Molar Volume	SV	cubic feet	385.32	
Mol. Wt. EO	MWEO	# / # mole	44.05	
Mol. Wt. H2O	MWH2O	# / # mole	18	
Mol. Wt. N2	MWN2	# / # mole	28	
Standard Temperature	Tstd	degree R	528	
Standard Barometric Pressure	Pstd	inch Hg	29.92	
Barometric Pressure	Pbar	inch Hg	30.1	
Conversion factor millibars to inches Hg			0.0295	
Conversion factor kg to pounds			2.2046	inch Hg
Chamber pressure after nitrogen wash		mbar	237.2881356	7.0
Chamber pressure after nitrogen wash		inch Hg	7.00	F F
Chamber temperature after nitrogen wash		degree C	53.9	130.0 128.0 129.0
Chamber temperature after nitrogen wash		degree R	589.0	
Volume nitrogen in chamber		cubic feet	314.64	
Pound moles nitrogen in chamber			0.91	
Mass nitrogen in chamber		pounds	25.35	inch Hg
Chamber pressure after humidification	P	mbar	271.1864407	8.0
Chamber pressure after humidification	P	inch Hg	8.00	
Pressure increase due to humidification	P	inch Hg	1.00	F F
Chamber temperature after humidification		degree C	53.9	129.0 129.0 129.0
Chamber temperature after humidification		degree R	589.0	
Volume H2O in chamber		cubic feet	44.95	
Pound Moles of H2O at chamber pressure			0.12	
Mass H2O at chamber pressure		pounds	2.10	lbs
Mass EtO charged to chamber		kg	27	60.40
Mass EtO charged to chamber	Wc	pounds	60.4	inch Hg
Chamber pressure after EtO injection		mbar	661.0169492	19.5
Chamber pressure after EtO injection		inch Hg	19.50	F F
Chamber Temperature after EtO injection		degree C	55.0	131.0 131.0 131.0
Chamber Temperature after EtO injection		degree R	591.0	
Chamber temperature after nitrogen blanket		degree R	591.0	
Total Moles N2 in chamber			0.91	
Total mass nitrogen in chamber		pounds	25.35	
Total volume gas in chamber		std. cubic feet	706.18	
Pound Moles EtO injected			1.37	
Weight % N2	WN2	%	28.86%	
Weight % water	WH2O	%	2.39%	
Weight % EtO	WEO	%	68.75%	
EtO mole fraction	%EOv	%	57.29%	
H2O mole fraction	%H2Ov	%	4.87%	
N2 mole fraction	%N2v	%	38.96%	inch Hg
Chamber pressure after evacuation		mbar	237.2881356	7.0
Chamber pressure after evacuation		inch Hg	7	F F
Chamber temperature after 1st evacuation		degree C	53.9	130.0 128.0 129.0
Chamber temperature after 1st evacuation		degree R	589.0	
Total volume gas in chamber		std. cubic feet	254.36	
Percent chamber gas evacuated		%	63.98%	
Residual Mass EtO remaining in chamber	Wr	pounds	21.76	
Mass EtO at Inlet to scrubber	Wi	pounds	38.64	
Concentration EtO in Scrubber Outlet	C	ppm	16.2	
Volume gas exiting scrubber	V	dscf	240.6	
Mass EtO exiting scrubber	Wb	pounds	0.00044	
Control Device Efficiency	% Eff	%	99.99885%	

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Customed, Inc. Fajardo, Puerto Rico				
Run No.	Two	Date	Thursday, January 9, 2020	
Barometric Pressure	30.00	in Hg	Moisture %	7.85%
Stack (Static) Pressure	0.15	in H ₂ O	mol wt stack gas Md	30.00
Diameter of Stack	4	inch	mol wt stack gas Ms	29.06
Elapsed Time (Minutes)	Stack Differential Pressure ("H ₂ O)	Stack Gas Temperature (°F)	Stack Gas Velocity (FPS)	Stack Gas Volumetric Flow (DSCF)
1801	0.010	82.0	6.67	31.45
1802	0.010	83.0	6.68	31.42
1803	0.005	87.0	4.74	22.14
1804	0.005	98.0	4.79	21.92
1805	0.005	105.0	4.82	21.78
1806	0.005	109.0	4.84	21.70
1807	0.005	109.0	4.84	21.70
1808	0.005	117.0	4.87	21.55
1809	0.005	120.0	4.88	21.50
1810	0.005	119.0	4.88	21.51
1810:11:00	0.005	119.0	4.88	3.94
Total				240.61
Average 106.6				

ATTACHMENT F

PROCESS RUN RECORDS

01/09/2000 CUSI

	Ts	DP
Start	0	86
0858	1	89
	2	95
	3	102
	4	108
	5	116
	6	118
	7	114
0906	8	116
	9	
	10	
	11	
	12	
	13	
	14	
	15	

TANK 1
72.5"

TANK 2
~~17.5~~
16.5 - 17.0"

43 lbs GTO V300

Pbar = 30' WD
x 0.15

Pg =

01/09/20 CUSTOMED SCRUBBER TEST #2

START MINUTES	ΔP	TEMP	TANK 1 72.2"	TANK 2 170"
1801	0	0.010	82	
	1	0.010	83	
	2	0.005	87	
	3	0.005	98	LBS Gto USED
	4	0.005	105	
	5	0.005	109	
	6	0.005	109	
	7	0.005	117	
	8	0.005	120	
	9	0.005	119	
	10	0.005	119	
	11			
	12			

P_{bar} 36.00

$P_S = 10^{15}$

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STERILIZATION PROCEDURE

FORM STP 002-02 Page 1 of 1

Revision A

02-03-15

SS

Effective Date

01-29-2015

02-03-15

Issued by:

Title: Sterilization Manager

Date: 01/29/15

Approved by:

Title: QA Lead

Date: 01-29-2015

TITLE: REGISTRO DE CONSUMO DE ETO

MONTH: December

YEAR: 2019

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Cycle No.:	Cycle No.:	Cycle No.:	Cycle No.	Cycle No.	Cycle No.	Cycle No.
Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb): 51	Qty.EtO(lb):	Qty.EtO(lb):
Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:
Cycle No. 19340	Cycle No. 19343	Cycle No.				
Qty.EtO(lb): 62.5	Qty.EtO(lb): 61.0	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):
Performed by: Date: 12-09-19	Performed by: Date: 12-09-19	Performed by: Date:				
Cycle No.	Cycle No.	Cycle No.	Cycle No.	Cycle No.	Cycle No.	Cycle No.
Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):
Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:
Cycle No.	Cycle No.	Cycle No.	Cycle No.	Cycle No.	Cycle No.	Cycle No.
Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):
Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:
Cycle No.	Cycle No.	Cycle No.	Cycle No.	Cycle No. 01-03-2	Cycle No.	Cycle No.
Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):
Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:

Week No.	1	2	3	4	5	Total Weight (lb)
Total Weight (lb.)	0	123.5	0	0	0	123.5

Verified by/Date:

01/28/2020

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STERILIZATION PROCEDURE

FORM STP 002-02 Page 1 of 1

Revision A

02-03-15

Effective Date

01-29-2015 02-03-15

Issued by: *J. Diaz M.*

Title: Sterilization Manager

Date: 01/29/15

Approved by: *J. Diaz M.*

Title: QA Lead

Date: 01-29-2015

TITLE: REGISTRO DE CONSUMO DE ETO

MONTH: November (2019)

YEAR: 2019

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Cycle No.: Qty.EtO(lb):	Cycle No.: Qty.EtO(lb):	Cycle No.: Qty.EtO(lb):	Cycle No.: Qty.EtO(lb):	Cycle No. 19304 Qty.EtO(lb): 60.5	Cycle No.: Qty.EtO(lb):	Cycle No.: Qty.EtO(lb):
Performed by: Date:	Performed by: Date:	Performed by: <i>A</i> Date: <i>1/15 11-01-19</i>	Performed by: Date:	Performed by: Date: <i>1/15 11-01-19</i>	Performed by: Date: <i>1/15 11-04-19</i>	Performed by: Date:
Cycle No. 19305 Qty.EtO(lb): 62.5	Cycle No. 19308 Qty.EtO(lb): 60.5	Cycle No. 19309 Qty.EtO(lb): 61.5	Cycle No. Qty.EtO(lb):	Cycle No. 19311 Qty.EtO(lb): 60.0	Cycle No. Qty.EtO(lb):	Cycle No. Qty. EtO.(lb):
Performed by: Date: <i>1/15 11-04-19</i>	Performed by: Date: <i>1/15 11-05-19</i>	Performed by: Date: <i>1/15 11-06-19</i>	Performed by: Date: <i>1/15 11-08-19</i>	Performed by: Date: <i>1/15 11-08-19</i>	Performed by: Date: <i>1/15 11-11-19</i>	Performed by; Date:
Cycle No. Qty.EtO(lb): <i>A</i>	Cycle No. 19315 Qty.EtO(lb): 62.0	Cycle No. Qty.EtO(lb): <i>A</i>	Cycle No. 19317 Qty.EtO(lb): 60.0	Cycle No. Qty.EtO(lb):	Cycle No. <i>JN</i> Qty.EtO(lb): <i>11-3-</i>	Cycle No. Qty.EtO(lb):
Performed by: Date: <i>1/15 11-04-19</i>	Performed by: Date: <i>1/15 11-02-19</i>	Performed by: Date: <i>1/15 11-04-19</i>	Performed by: Date: <i>1/15 11-04-19</i>	Performed by: Date:	Performed by: Date:	Performed by: Date:
Cycle No. <i>JN</i> Qty.EtO(lb): <i>11-2-10</i>	Cycle No. 19322 Qty.EtO(lb): 58.5	Cycle No. 19323 Qty.EtO(lb): 60.0	Cycle No. Qty.EtO(lb):	Cycle No. Qty.EtO(lb): <i>A</i>	Cycle No. Qty.EtO(lb):	Cycle No. Qty.EtO.(lb):
Performed by: Date: <i>1/15 11-04-19</i>	Performed by: Date: <i>1/15 11-02-19</i>	Performed by: <i>JN</i> Date: <i>11-20-19</i>	Performed by: Date:	Performed by: Date: <i>1/15 11-26-19</i>	Performed by: Date: <i>1/15 11-26-19</i>	Performed by: Date:
Cycle No. Qty.EtO(lb): <i>A</i>	Cycle No. 19329 Qty.EtO(lb): 60.5	Cycle No. Qty.EtO(lb):	Cycle No. Qty.EtO(lb): <i>A</i>	Cycle No. Qty.EtO(lb): <i>A</i>	Cycle No. Qty.EtO(lb):	Cycle No. Qty.EtO.(lb):
Performed by: Date: <i>1/26-19</i>	Performed by: Date: <i>1/15 11-04-19</i>	Performed by: Date:	Performed by: Date:	Performed by: Date: <i>1/15 11-02-19</i>	Performed by: Date: <i>1/15 11-02-19</i>	Performed by: Date:

Week No.	1	2	3	4	5	Total Weight (lb)
Total Weight (lb.)	60.5	244.5	127.0	118.5	60.5	611

Verified by/Date: *J.D 12-02-19*

01/28/2020

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STERILIZATION PROCEDURE

FORM STP 002-02 Page 1 of 1

Revision A

02-03-15

Effective Date

01-29-2015 02-03-15

Issued by: *[Signature]*

Title: Sterilization Manager

Date: 01/29/15Approved by: *[Signature]*

Title: QA Lead

Date: 01-29-2015**TITLE: REGISTRO DE CONSUMO DE ETO**MONTH: OctoberYEAR: 2019

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Cycle No.: <u>19277</u>	Cycle No.: <u>19280</u>	Cycle No.: <u>19274</u>	Cycle No. <u>19275</u>	Cycle No. <u>19276</u>	Cycle No. <u>19276</u>	Cycle No.
Qty.EtO(lb): <u>63.0</u>	Qty.EtO(lb): <u>62.0</u>	Qty.EtO(lb): <u>63.0</u>	Qty.EtO(lb): <u>62.0</u>	Qty.EtO(lb): <u>62.5</u>	Qty.EtO(lb): <u>62.5</u>	Qty.EtO(lb):
Performed by: Date: <u>10-02-19</u>	Performed by: Date: <u>10-02-19</u>	Performed by: Date: <u>10-02-19</u>	Performed by: Date: <u>10-03-19</u>	Performed by: Date: <u>10-04-19</u>	Performed by: Date: <u>10-05-19</u>	Performed by Date:
Cycle No. <u>19277</u>	Cycle No. <u>19281</u>	Cycle No. <u>19281</u>	Cycle No. <u>19282</u>	Cycle No. <u>19283</u>	Cycle No.	Cycle No.
Qty.EtO(lb): <u>63.0</u>	Qty.EtO(lb): <u>62.0</u>	Qty.EtO(lb): <u>60.0</u>	Qty.EtO(lb): <u>63.5</u>	Qty.EtO(lb): <u>62.5</u>	Qty.EtO(lb): <u>62.5</u>	Qty.EtO(lb):
Performed by: Date: <u>10-07-19</u>	Performed by: Date: <u>10-08-19</u>	Performed by: Date: <u>10-09-19</u>	Performed by: Date: <u>10-10-19</u>	Performed by: Date: <u>10-11-19</u>	Performed by: Date: <u>10-12-19</u>	Performed by; Date;
Cycle No. <u>19288</u>	Cycle No. <u>19288</u>	Cycle No. <u>19288</u>	Cycle No.	Cycle No. <u>19290</u>	Cycle No.	Cycle No.
Qty.EtO(lb): <u>A</u>	Qty.EtO(lb): <u>A</u>	Qty.EtO(lb): <u>59.5</u>	Qty.EtO(lb):	Qty.EtO(lb): <u>61.0</u>	Qty.EtO(lb): <u>61.0</u>	Qty.EtO(lb):
Performed by: Date: <u>10-15-19</u>	Performed by: Date:	Performed by: Date: <u>10-16-19</u>	Performed by: Date: <u>10-17-19</u>	Performed by: Date: <u>10-18-19</u>	Performed by: Date: <u>10-19-19</u>	Performed by: Date:
Cycle No. <u>19296</u>	Cycle No. <u>19297</u>	Cycle No. <u>19296</u>	Cycle No. <u>19296</u>	Cycle No. <u>19297</u>	Cycle No.	Cycle No.
Qty.EtO(lb): <u>A</u>	Qty.EtO(lb): <u>A</u>	Qty.EtO(lb): <u>A</u>	Qty.EtO(lb): <u>61.0</u>	Qty.EtO(lb): <u>60.0</u>	Qty.EtO(lb): <u>A</u>	Qty.EtO(lb):
Performed by: Date: <u>10-24-19</u>	Performed by: Date: <u>10-24-19</u>	Performed by: Date:	Performed by: Date: <u>10-24-19</u>	Performed by: Date: <u>10-25-19</u>	Performed by: Date: <u>10-25-19</u>	Performed by: Date:
Cycle No. <u>19301</u>	Cycle No. <u>19303</u>	Cycle No. <u>19301</u>	Cycle No. <u>19303</u>	Cycle No.	Cycle No.	Cycle No.
Qty.EtO(lb): <u>A</u>	Qty.EtO(lb): <u>62.0</u>	Qty.EtO(lb): <u>62.0</u>	Qty.EtO(lb): <u>63.5</u>	Qty.EtO(lb): <u>A</u>	Qty.EtO(lb): <u>A</u>	Qty.EtO(lb):
Performed by: Date: <u>10-30-19</u>	Performed by: Date:	Performed by: Date: <u>10-30-19</u>	Performed by: Date: <u>10-31-19</u>	Performed by: Date: <u>10-31-19</u>	Performed by: Date: <u>10-31-19</u>	Performed by: Date:

Week No.	1	2	3	4	5	Total Weight (lb)
Total Weight (lb.)	<u>187.5</u>	<u>311</u>	<u>120.5</u>	<u>121.0</u>	<u>125.5</u>	<u>865.5</u>

Verified by/Date: 7/10/19-31-19

Page 118 of 155

From: Juan C. Pacheco jpacheco@prhospital.com
Subject: PH
Date: January 9, 2020 at 12:40 PM
To: Ruben Martinez Vargas ruben.martinez@prhospital.com
Cc: Jose Becerril jose.becerril@prhospital.com



Saludos,

El PH inicial fue de .44 a .45 PH.

Luego de anadir 40 gal de Ácido Sulfúrico y anadir agua es de .44 PH.

Juan C. Pacheco

Tel. (787) 622-5151 Ext. 7110

cel. (787) 435-7723

Email: jpacheco@prhospital.com

Customed Inc.

EQUIPMENT INSTALLATION QUALIFICATION
Sterilizer Chamber Page 6 of 29

EQUIPMENT INFORMATION

Equipment Description

1. Manufacturer Vacudyne Company
Address: 375 E. Joe Orr Road
Chicago Heights, Illinois 60411
Phone: (708) 751-5200 Fax (708) 751-7180

2. Contract Number J02 - 38
3. Serial Number J02-38
4. Location Calle Igualdad #7, Fajardo, P.R.
5. Asset Number
6. Vessel Dimensions 8'H X 4'7"1/8 W X 33'D (Cubic Meters = 35.3147 cu. ft)

Manufacturer's Specifications

1. Copy Available Chamber Blueprint
2. Location CONTROL ROOM
3. Verify that all labelling and tagging is complete.
Record ASME N.B. numbers and dates.

Chamber: Max WP full vacuum to 15 PSI Max Temp 200 °F
Jacket: Nat'l BD No
Comments: Year Built 2002

Materials of Construction (Product Contact)

Component	Material	Contact
CHAMBER	<u>Black Iron coated with 304 SS</u>	<u>Y</u> <u>N</u> <u>X</u>
PIPING-EO CONTACT LINES	<u>304-3/16 SS (stainless Steel)</u>	<u>Y</u> <u>N</u> <u>X</u>
VALVES	<u>304 SS</u>	<u>Y</u> <u>N</u> <u>X</u>
STEAM PIPING	<u>Black Iron with SS and Brass valves</u>	<u>Y</u> <u>N</u> <u>X</u>
PNEUMATIC LINES	<u>Copper</u>	<u>Y</u> <u>N</u> <u>X</u>

Comment: No Comments.

Researched/Reviewed By

Date

12/13/04

Copyright By Consulting And Technical Services, Inc.
October 3, 2004 Protocol # 04107015

EE
DATE 01/09/20 Thu CYCLE 125 PROGRAM VERSION 4E-2 CHECK VALUE 13180
RUN ID # SL20008 OPERATOR A.Alicea

Customed Inc.

PROCESS PARAMETERS

CHAMBER TEMP 130 F, LO TOL 10 F, HI TOL 10 F, ABORT 165 F
INITIAL EVACUATION A 7.0 INHG, 2.01 INHG/MIN
HUMIDITY INJECTION A 1.0 INHG
NITROGEN BLANKET A 25.0 INHG, 1.00 INHG/MIN
NITROGEN DILUTION 2 CYCLES, RH 0:30 HH:MM, 55 % RH, UPPER 25.0 INHG, LOWER 22.0 INHG
INITIAL EVACUATION B 7.0 INHG, 2.01 INHG/MIN
HUMIDITY INJECTION B 1.0 INHG
HUMIDITY DWELL 1:05 HH:MM, 8.0 INHG, LO 7.5 INHG, HI 8.5 INHG, MAX 9.0 INHG
STERILANT INJECTION 19.5 INHG, 0.71 INHG/MIN
EXPOSURE 3:05 HH:MM, 19.5 INHG, LO 19.0 INHG, HI 20.0 INHG, ABORT 21.5 INHG
LO 5 F, HI 5 F, ABORT 145 F, MAKEUPS: STERILANT
STERILANT REMOVAL EXHAUST 0.0 SKIP, EVACUATION 7.0 INHG, 2.01 INHG/MIN
NITROGEN WASH 3 CYCLES, EVAC DWELL 0:00 HH:MM, UPPER 20.0 INHG, LOWER 7.0 INHG
AIR WASH A 3 CYCLES, EVAC DWELL 0:00 HH:MM, UPPER 20.0 INHG, LOWER 7.0 INHG
FINAL AIRBREAK 27.0 INHG, 2.01 INHG/MIN

E	TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
---	------	------	----------	----	---------	-------------------	--------------

INITIAL EVACUATION A PHASE

E 11:48	124 F	30.1 INHG	31 %	104 F			
E 11:50	124 F	26.0 INHG	33 %	105 F			
E 11:52	124 F	22.0 INHG	35 %	105 F			
E 11:54	124 F	18.0 INHG	36 %	105 F			
E 11:56	124 F	14.2 INHG	36 %	105 F			
E 11:58	125 F	11.0 INHG	36 %	106 F			
E 11:58	125 F	10.8 INHG	36 %	106 F	SLOW INCREMENT		
E 12:00	125 F	8.6 INHG	36 %	106 F			
E 12:02	125 F	7.0 INHG	36 %	106 F			
MAX:	125 F	-23.1 INHG	36 %		PHASE 0:13	PHASE ELAPSED 0:13	
MIN:	124 F	(CHANGE)	31 %		CYCLE	0:13	

HUMIDITY INJECTION A (PRESS) PHASE

E 12:02	125 F	7.0 INHG	36 %	106 F			
E 12:02	126 F	8.0 INHG	50 %	110 F			
MAX:	126 F	1.0 INHG	50 %		PHASE 0:00	PHASE ELAPSED 0:00	
MIN:	125 F	(CHANGE)	36 %		CYCLE	0:14	

NITROGEN BLANKET A PHASE

E 12:02	126 F	8.0 INHG	56 %	114 F			
E 12:04	127 F	10.2 INHG	100 %	107 F			
E 12:06	128 F	12.2 INHG	88 %	110 F			
E 12:08	128 F	14.2 INHG	75 %	112 F			

(1)

E01/09/20 Thu CYCLE 125

RUN ID # SL20008

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
E 12:10	128 F	16.2 INHG	70 %	114 F		
E 12:12	128 F	18.3 INHG	66 %	116 F		
E 12:14	128 F	20.3 INHG	65 %	117 F		
E 12:16	128 F	22.3 INHG	63 %	117 F		
E 12:18	129 F	24.3 INHG	62 %	118 F		
E 12:19	128 F	25.0 INHG	62 %	118 F		
MAX:	129 F	17.0 INHG	100 %		PHASE 0:16	PHASE ELAPSED 0:16
MIN:	126 F	(CHANGE)	50 %		CYCLE	0:30

NITROGEN DILUTION (WASH) PHASE

E 12:19	128 F	25.0 INHG	62 %	118 F	BEGIN RH	1
E 12:19	128 F	25.0 INHG	62 %	118 F		
E 12:21	128 F	25.2 INHG	61 %	117 F		
E 12:23	128 F	25.2 INHG	63 %	116 F		
E 12:25	128 F	25.2 INHG	65 %	115 F		
E 12:27	128 F	25.3 INHG	67 %	114 F		
E 12:29	128 F	25.3 INHG	68 %	114 F		
E 12:31	128 F	25.3 INHG	69 %	113 F		
E 12:33	128 F	25.3 INHG	70 %	113 F		
E 12:35	128 F	25.3 INHG	70 %	112 F		
E 12:37	129 F	25.3 INHG	71 %	112 F		
E 12:39	129 F	25.3 INHG	72 %	111 F		
E 12:41	129 F	25.3 INHG	72 %	111 F		
E 12:43	129 F	25.4 INHG	72 %	111 F		
E 12:45	129 F	25.4 INHG	73 %	110 F		
E 12:47	129 F	25.4 INHG	73 %	110 F		
E 12:49	129 F	25.4 INHG	73 %	110 F		
E 12:49	129 F	25.4 INHG	73 %	110 F	BEGIN NITROGEN	1
E 12:49	129 F	25.4 INHG	73 %	110 F	BEGIN EVACUATION	1
E 12:50	129 F	22.0 INHG	68 %	110 F	BEGIN RH	2
E 12:51	129 F	21.9 INHG	66 %	110 F		
E 12:53	129 F	22.0 INHG	69 %	110 F		
E 12:55	129 F	22.0 INHG	70 %	110 F		
E 12:57	129 F	22.0 INHG	71 %	110 F		
E 12:59	129 F	22.1 INHG	72 %	109 F		
E 13:01	129 F	22.1 INHG	72 %	109 F		
E 13:03	130 F	22.1 INHG	73 %	109 F		
E 13:05	130 F	22.1 INHG	73 %	109 F		
E 13:07	130 F	22.1 INHG	73 %	109 F		
E 13:09	130 F	22.2 INHG	73 %	109 F		
E 13:11	130 F	22.2 INHG	73 %	109 F		
E 13:13	130 F	22.2 INHG	74 %	109 F		
E 13:15	130 F	22.2 INHG	74 %	109 F		
E 13:17	130 F	22.2 INHG	74 %	109 F		
E 13:19	130 F	22.2 INHG	74 %	109 F		
E 13:20	130 F	22.2 INHG	74 %	109 F	BEGIN NITROGEN	2
E 13:21	130 F	23.4 INHG	75 %	111 F	BEGIN EVACUATION	2
E 13:23	130 F	25.0 INHG	73 %	114 F		
E 13:23	130 F	25.1 INHG	73 %	115 F		

E01/09/20 Thu CYCLE 125

RUN ID # SL200008

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN		
E 13:24	130 F	22.0 INHG	65 %	114 F				
MAX:	130 F	-3.0 INHG	75 %		PHASE 1:05	PHASE ELAPSED 1:05		
MIN:	128 F	(CHANGE)	61 %			CYCLE 1:35		

INITIAL EVACUATION B PHASE

E 13:24	130 F	21.9 INHG	64 %	114 F				
E 13:26	129 F	17.8 INHG	58 %	112 F				
E 13:28	129 F	14.1 INHG	55 %	112 F				
E 13:29	129 F	12.2 INHG	53 %	112 F	SLOW INCREMENT			
E 13:30	128 F	10.9 INHG	52 %	112 F				
E 13:32	129 F	8.6 INHG	50 %	112 F				
E 13:34	129 F	7.0 INHG	49 %	112 F				
MAX:	130 F	-15.0 INHG	64 %		PHASE 0:09	PHASE ELAPSED 0:09		
MIN:	128 F	(CHANGE)	49 %			CYCLE 1:45		

HUMIDITY INJECTION B (PRESS) PHASE

E 13:34	129 F	7.0 INHG	49 %	112 F				
E 13:34	129 F	8.0 INHG	62 %	117 F				
MAX:	129 F	1.0 INHG	62 %		PHASE 0:00	PHASE ELAPSED 0:00		
MIN:	129 F	(CHANGE)	49 %			CYCLE 1:46		

HUMIDITY DWELL (PRESS) PHASE

E 13:34	129 F	8.0 INHG	62 %	121 F				
E 13:36	130 F	8.1 INHG	100 %	127 F				
E 13:38	130 F	8.0 INHG	100 %	124 F				
E 13:40	131 F	7.9 INHG	95 %	121 F				
E 13:42	131 F	7.9 INHG	92 %	120 F				
E 13:44	131 F	7.9 INHG	90 %	119 F				
E 13:46	131 F	7.9 INHG	89 %	118 F				
E 13:48	131 F	8.0 INHG	88 %	117 F				
E 13:50	131 F	8.0 INHG	87 %	116 F				
E 13:52	131 F	8.0 INHG	87 %	115 F				
E 13:54	131 F	8.0 INHG	86 %	114 F				
E 13:56	131 F	8.0 INHG	86 %	114 F				
E 13:58	131 F	8.0 INHG	85 %	113 F				
E 14:00	131 F	8.0 INHG	85 %	113 F				
E 14:02	131 F	8.0 INHG	85 %	112 F				
E 14:04	131 F	8.0 INHG	84 %	112 F				
E 14:06	131 F	8.0 INHG	84 %	112 F				
E 14:08	131 F	8.0 INHG	84 %	111 F				
E 14:10	131 F	8.0 INHG	84 %	111 F				
E 14:12	131 F	8.0 INHG	84 %	111 F				
E 14:14	131 F	8.0 INHG	83 %	111 F				
E 14:16	131 F	8.0 INHG	83 %	110 F				

E01/09/20 Thu

CYCLE 125

RUN ID # SL20008

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
E 14:18	131 F	8.0 INHG	83 %	110 F		
E 14:20	131 F	8.0 INHG	83 %	110 F		
E 14:22	131 F	8.0 INHG	83 %	110 F		
E 14:24	131 F	8.1 INHG	83 %	110 F		
E 14:26	131 F	8.1 INHG	83 %	110 F		
E 14:28	131 F	8.1 INHG	82 %	110 F		
E 14:30	131 F	8.1 INHG	82 %	110 F		
E 14:32	131 F	8.1 INHG	82 %	110 F		
E 14:34	131 F	8.1 INHG	82 %	110 F		
E 14:36	131 F	8.1 INHG	82 %	110 F		
E 14:38	131 F	8.1 INHG	82 %	110 F		
E 14:39	131 F	8.1 INHG	81 %	110 F		
MAX:	131 F	0.0 INHG	100 %		PHASE	1:05
MIN:	129 F	(CHANGE)	62 %		PHASE ELAPSED	1:05
					CYCLE	2:51

STERILANT INJECTION PHASE

E 14:39	131 F	8.1 INHG	81 %	110 F		
E 14:41	131 F	9.6 INHG	91 %	111 F		
E 14:43	131 F	11.0 INHG	88 %	114 F		
E 14:45	131 F	12.4 INHG	83 %	116 F		
E 14:47	131 F	13.9 INHG	81 %	118 F		
E 14:49	131 F	15.3 INHG	78 %	118 F		
E 14:51	131 F	16.7 INHG	76 %	120 F		
E 14:53	131 F	18.1 INHG	72 %	121 F		
E 14:55	131 F	19.5 INHG	71 %	122 F		
MAX:	131 F	11.4 INHG	91 %		PHASE	0:15
MIN:	131 F	(CHANGE)	71 %		PHASE ELAPSED	0:15
STERILANT USED THIS PHASE:	54.6 LB,	CYCLE TOTAL:	54.6 LB		CYCLE	3:07

EXPOSURE PHASE

E 14:56	131 F	19.5 INHG	71 %	122 F	
E 14:58	130 F	19.4 INHG	68 %	119 F	
E 15:00	130 F	19.4 INHG	70 %	118 F	
E 15:02	130 F	19.3 INHG	71 %	118 F	
E 15:04	130 F	19.3 INHG	72 %	117 F	
E 15:06	130 F	19.3 INHG	73 %	116 F	
E 15:08	131 F	19.3 INHG	74 %	116 F	
E 15:10	131 F	19.2 INHG	75 %	115 F	
E 15:12	131 F	19.2 INHG	76 %	115 F	
E 15:12	131 F	19.5 INHG	76 %	116 F	GAS ADDITION 1 COMPLETE
E 15:14	131 F	19.6 INHG	76 %	116 F	
E 15:16	131 F	19.6 INHG	76 %	114 F	
E 15:18	131 F	19.5 INHG	77 %	114 F	
E 15:20	131 F	19.5 INHG	77 %	113 F	
E 15:22	131 F	19.5 INHG	78 %	113 F	
E 15:24	131 F	19.5 INHG	78 %	113 F	
E 15:26	130 F	19.5 INHG	78 %	112 F	
E 15:28	130 F	19.4 INHG	79 %	112 F	

E01/09/20 Thu

CYCLE 125

RUN ID # SL20008

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
E 15:30	130 F	19.4 INHGA	79 %	112 F		
E 15:32	131 F	19.4 INHGA	79 %	112 F		
E 15:34	131 F	19.4 INHGA	80 %	112 F		
E 15:36	131 F	19.4 INHGA	80 %	111 F		
E 15:38	131 F	19.4 INHGA	80 %	111 F		
E 15:40	131 F	19.4 INHGA	80 %	111 F		
E 15:42	131 F	19.3 INHGA	80 %	111 F		
E 15:44	131 F	19.3 INHGA	81 %	111 F		
E 15:46	131 F	19.3 INHGA	81 %	111 F		
E 15:48	131 F	19.3 INHGA	81 %	111 F		
E 15:50	131 F	19.3 INHGA	81 %	111 F		
E 15:52	131 F	19.3 INHGA	81 %	111 F		
E 15:54	131 F	19.3 INHGA	81 %	111 F		
E 15:56	131 F	19.3 INHGA	81 %	111 F		
E 15:58	131 F	19.3 INHGA	81 %	111 F		
E 16:00	131 F	19.3 INHGA	82 %	110 F		
E 16:02	131 F	19.2 INHGA	82 %	110 F		
E 16:04	131 F	19.2 INHGA	82 %	110 F		
E 16:06	131 F	19.2 INHGA	82 %	110 F		
E 16:08	131 F	19.2 INHGA	82 %	110 F		
E 16:10	131 F	19.2 INHGA	82 %	110 F		
E 16:12	131 F	19.2 INHGA	82 %	110 F		
E 16:13	131 F	19.5 INHGA	82 %	110 F	GAS ADDITION 2 COMPLETE	
E 16:14	131 F	19.6 INHGA	83 %	113 F		
E 16:16	131 F	19.6 INHGA	81 %	111 F		
E 16:18	131 F	19.6 INHGA	82 %	110 F		
E 16:20	131 F	19.6 INHGA	82 %	110 F		
E 16:22	131 F	19.5 INHGA	82 %	110 F		
E 16:24	131 F	19.5 INHGA	82 %	110 F		
E 16:26	131 F	19.5 INHGA	82 %	110 F		
E 16:28	131 F	19.5 INHGA	82 %	110 F		
E 16:30	131 F	19.5 INHGA	82 %	110 F		
E 16:32	130 F	19.5 INHGA	83 %	110 F		
E 16:34	130 F	19.5 INHGA	83 %	110 F		
E 16:36	130 F	19.5 INHGA	83 %	110 F		
E 16:38	130 F	19.5 INHGA	83 %	110 F		
E 16:40	130 F	19.5 INHGA	83 %	110 F		
E 16:42	130 F	19.4 INHGA	83 %	110 F		
E 16:44	130 F	19.4 INHGA	83 %	110 F		
E 16:46	130 F	19.4 INHGA	83 %	110 F		
E 16:48	130 F	19.4 INHGA	83 %	110 F		
E 16:50	130 F	19.4 INHGA	83 %	110 F		
E 16:52	130 F	19.4 INHGA	83 %	110 F		
E 16:54	130 F	19.4 INHGA	83 %	110 F		
E 16:56	130 F	19.4 INHGA	83 %	110 F		
E 16:58	130 F	19.4 INHGA	83 %	110 F		
E 17:00	130 F	19.4 INHGA	83 %	110 F		
E 17:02	130 F	19.4 INHGA	83 %	110 F		
E 17:04	130 F	19.4 INHGA	83 %	110 F		
E 17:06	130 F	19.3 INHGA	83 %	110 F		
E 17:08	130 F	19.3 INHGA	84 %	110 F		
E 17:10	130 F	19.3 INHGA	84 %	110 F		
E 17:12	130 F	19.3 INHGA	84 %	110 F		
E 17:14	130 F	19.3 INHGA	84 %	110 F		
E 17:16	130 F	19.3 INHGA	84 %	110 F		
E 17:18	130 F	19.3 INHGA	84 %	110 F		

E01/09/20 Thu

CYCLE 125

RUN ID # SL20008

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
E 17:20	130 F	19.3 INHG	84 %	110 F		
E 17:22	130 F	19.3 INHG	84 %	110 F		
E 17:24	130 F	19.3 INHG	84 %	110 F		
E 17:26	130 F	19.3 INHG	84 %	110 F		
E 17:28	130 F	19.3 INHG	84 %	110 F		
E 17:30	130 F	19.3 INHG	84 %	110 F		
E 17:32	130 F	19.3 INHG	84 %	110 F		
E 17:34	130 F	19.3 INHG	84 %	110 F		
E 17:36	130 F	19.3 INHG	84 %	110 F		
E 17:38	130 F	19.3 INHG	84 %	110 F		
E 17:40	130 F	19.2 INHG	84 %	110 F		
E 17:42	130 F	19.2 INHG	84 %	110 F		
E 17:44	130 F	19.2 INHG	84 %	110 F		
E 17:46	130 F	19.2 INHG	85 %	110 F		
E 17:48	130 F	19.2 INHG	85 %	110 F		
E 17:50	130 F	19.2 INHG	85 %	110 F		
E 17:52	130 F	19.2 INHG	85 %	110 F		
E 17:54	130 F	19.2 INHG	85 %	110 F		
E 17:56	130 F	19.2 INHG	85 %	110 F		
E 17:56	130 F	19.5 INHG	85 %	107 F	GAS ADDITION 3 COMPLETE	
E 17:58	130 F	19.6 INHG	85 %	111 F		
E 18:00	130 F	19.6 INHG	84 %	109 F		
E 18:01	130 F	19.6 INHG	84 %	109 F		
MAX:	131 F	0.1 INHG	85 %		PHASE 3:05	PHASE ELAPSED 3:05
MIN:	130 F	(CHANGE)	68 %		CYCLE 6:12	
STERILANT USED THIS PHASE:		5.8 LB,		CYCLE TOTAL: 60.4 LB		

STERILANT REMOVAL PHASE

E 18:01	130 F	19.6 INHG	84 %	109 F		
E 18:01	130 F	19.6 INHG	84 %	109 F	BEGIN EVACUATION	
E 18:03	130 F	15.7 INHG	76 %	109 F		
E 18:05	129 F	12.4 INHG	70 %	109 F		
E 18:05	129 F	12.3 INHG	70 %	109 F	SLOW INCREMENT	
E 18:07	129 F	10.0 INHG	66 %	109 F		
E 18:09	129 F	8.1 INHG	63 %	109 F		
E 18:10	128 F	7.0 INHG	61 %	109 F		
MAX:	130 F	-12.6 INHG	84 %		PHASE 0:09	PHASE ELAPSED 0:09
MIN:	128 F	(CHANGE)	61 %		CYCLE 6:22	

NITROGEN WASH (WASH) PHASE

E 18:10	128 F	7.0 INHG	61 %	109 F		
E 18:10	128 F	7.0 INHG	61 %	109 F	BEGIN NITROGEN	1
E 18:12	129 F	9.2 INHG	52 %	108 F		
E 18:14	129 F	11.2 INHG	49 %	109 F		
E 18:16	129 F	13.2 INHG	48 %	111 F		
E 18:18	129 F	15.2 INHG	49 %	114 F		
E 18:20	129 F	17.2 INHG	49 %	115 F		
E 18:22	129 F	19.2 INHG	50 %	116 F		

E01/09/20 Thu CYCLE 125

RUN ID # SL20008

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
E 18:23	129 F	20.0 INHG	49 %	116 F		BEGIN EVACUATION 1
E 18:24	129 F	16.8 INHG	45 %	116 F		
E 18:26	128 F	13.1 INHG	44 %	115 F		
E 18:27	128 F	12.3 INHG	43 %	115 F	SLOW INCREMENT	
E 18:28	128 F	10.2 INHG	43 %	114 F		
E 18:30	128 F	8.1 INHG	43 %	114 F		
E 18:32	128 F	7.0 INHG	43 %	113 F		BEGIN NITROGEN 2
E 18:32	129 F	8.2 INHG	44 %	109 F		
E 18:34	129 F	10.2 INHG	43 %	109 F		
E 18:36	129 F	12.2 INHG	42 %	111 F		
E 18:38	129 F	14.2 INHG	42 %	114 F		
E 18:40	129 F	16.2 INHG	42 %	115 F		
E 18:42	129 F	18.2 INHG	41 %	117 F		
E 18:44	129 F	20.0 INHG	41 %	118 F		BEGIN EVACUATION 2
E 18:44	129 F	19.5 INHG	41 %	118 F		
E 18:46	129 F	15.4 INHG	37 %	117 F		
E 18:48	128 F	11.8 INHG	37 %	116 F		
E 18:49	128 F	10.7 INHG	37 %	116 F	SLOW INCREMENT	
E 18:50	128 F	9.2 INHG	38 %	115 F		
E 18:52	128 F	7.2 INHG	38 %	115 F		
E 18:53	128 F	7.0 INHG	38 %	114 F		BEGIN NITROGEN 3
E 18:54	129 F	9.2 INHG	42 %	111 F		
E 18:56	129 F	11.2 INHG	39 %	111 F		
E 18:58	129 F	13.2 INHG	38 %	113 F		
E 19:00	129 F	15.2 INHG	37 %	116 F		
E 19:02	130 F	17.2 INHG	37 %	117 F		
E 19:04	130 F	19.2 INHG	37 %	118 F		
E 19:05	130 F	20.0 INHG	37 %	118 F		BEGIN EVACUATION 3
E 19:06	129 F	17.4 INHG	33 %	118 F		
E 19:08	128 F	13.5 INHG	33 %	117 F		
E 19:10	128 F	10.7 INHG	34 %	116 F	SLOW INCREMENT	
E 19:10	128 F	10.4 INHG	34 %	116 F		
E 19:12	128 F	8.1 INHG	36 %	115 F		
E 19:14	128 F	7.0 INHG	36 %	115 F		
MAX:	130 F	0.0 INHG	61 %		PHASE 1:03	PHASE ELAPSED 1:03
MIN:	128 F	(CHANGE)	33 %		CYCLE 7:25	

AIR WASH A (WASH) PHASE

E 19:14	128 F	7.0 INHG	36 %	115 F		
E 19:14	128 F	7.0 INHG	36 %	115 F	BEGIN INBLEED	1
E 19:16	130 F	11.5 INHG	36 %	114 F		
E 19:18	130 F	15.5 INHG	35 %	114 F		
E 19:20	130 F	19.5 INHG	36 %	113 F		
E 19:20	130 F	20.0 INHG	35 %	113 F		BEGIN EVACUATION 1
E 19:22	129 F	16.2 INHG	32 %	113 F		
E 19:24	128 F	12.7 INHG	34 %	112 F		
E 19:25	128 F	10.7 INHG	34 %	112 F	SLOW INCREMENT	
E 19:26	128 F	9.7 INHG	34 %	112 F		
E 19:28	128 F	7.6 INHG	34 %	112 F		
E 19:28	128 F	7.0 INHG	35 %	112 F	BEGIN INBLEED	2
E 19:30	129 F	11.1 INHG	34 %	111 F		
E 19:32	130 F	15.0 INHG	33 %	111 F		

E01/09/20 Thu CYCLE 125

RUN ID # SL200008

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
E 19:34	130 F	18.9 INHG	32 %	111 F		
E 19:34	130 F	20.1 INHG	33 %	111 F		BEGIN EVACUATION 2
E 19:36	129 F	17.9 INHG	31 %	111 F		
E 19:38	128 F	14.0 INHG	31 %	111 F		
E 19:40	128 F	10.8 INHG	32 %	111 F	SLOW INCREMENT	
E 19:40	128 F	10.8 INHG	32 %	111 F		
E 19:42	128 F	8.4 INHG	32 %	110 F		
E 19:43	128 F	7.0 INHG	33 %	110 F		BEGIN INBLEED 3
E 19:44	129 F	9.6 INHG	37 %	110 F		
E 19:46	130 F	13.6 INHG	32 %	110 F		
E 19:48	130 F	17.6 INHG	32 %	110 F		
E 19:49	130 F	20.1 INHG	32 %	110 F		BEGIN EVACUATION 3
E 19:50	130 F	19.9 INHG	32 %	110 F		
E 19:52	129 F	15.5 INHG	29 %	110 F		
E 19:54	128 F	11.8 INHG	30 %	110 F		
E 19:54	128 F	10.7 INHG	30 %	110 F	SLOW INCREMENT	
E 19:56	128 F	9.1 INHG	30 %	110 F		
E 19:58	128 F	7.1 INHG	31 %	110 F		
E 19:58	128 F	7.0 INHG	31 %	110 F		
MAX:	130 F	0.0 INHG	37 %		PHASE 0:44	PHASE ELAPSED 0:44
MIN:	128 F	(CHANGE)	29 %		CYCLE 8:09	

FINAL AIRBREAK PHASE

E 19:58	128 F	7.0 INHG	31 %	110 F		
E 20:00	130 F	11.5 INHG	30 %	110 F		
E 20:02	130 F	15.5 INHG	30 %	110 F		
E 20:04	130 F	19.4 INHG	31 %	109 F		
E 20:06	130 F	23.4 INHG	32 %	109 F		
E 20:07	130 F	27.0 INHG	32 %	109 F		
MAX:	130 F	20.0 INHG	32 %		PHASE 0:09	PHASE ELAPSED 0:09
MIN:	128 F	(CHANGE)	30 %		CYCLE 8:19	

END OF CYCLE PHASE

20:07

TOTAL CYCLE 8:18 CYCLE ELAPSED 8:19

OPERATOR J. J. - 01-09-20ACCEPT C NON CONFORMANCE _____Q.A. _____ DATE _____
SUPERVISOR _____

(8)

STERILIZATION PROCEDURE (STP)

Issued by J.D.Y-J Title: QA/Doc. Control Date: 06-06-19
Approved by: R. Vazquez Title: QA Director Date: 06-14-19

TITLE: FORMA PARA REGISTRO PARA CICLO DE ESTERILIZACION**PARA USO DEL DEPARTAMENTO DE CALIDAD**Num. de Lote de Carga SL # 20008

Para Productos: Ver Forma STP 002-03

Procedimiento Etapa de Pre-acondicionamiento: STP 003Procedimiento Proceso de Esterilización: STP 002, STP 010Procedimiento Etapa de Aireación: STP 004 Full Cycle (Soft Cycle 125) Ciclo contiene productos a ser re-esterilizados (Soft Cycle 125) Validation Half Cycle (Soft Cycle 126)BI's Lot # 0259, expiration date: 07-25-20Cantidad de BI's Utilizados: 32 + (Control positivo: 1 BI) = 33 Total:Documento Completado y BI's Ubicados por/Fecha: Pablo Pizarro 01-08-20Verificado por/Fecha: J. Vazquez 01-08-20**Etapa de Pre – Acondicionamiento****Comienzo de Etapa de Pre Acondicionamiento**Realizado por/Fecha: J. Vazquez 01-08-20 Hora: 05:57 AM PMVerificado por/Fecha: J. Vazquez 01-08-20**Finalización de Etapa de Pre Acondicionamiento**

Verifique y marque con marca de cotejo (Si o No) que los parámetros de temperatura y humedad relativa y tiempo de exposición son aceptables:

Parámetros de ciclo 125 (Soft cycle): Temperatura: **115° F ± 9°F**, Humedad: **65%RH ± 15%RH**, Tiempo exposición mínimo a parámetros de temperatura / humedad: **12 horas**.Parámetros aceptables: **SI NO** Hora de transferencia de la 1ra paleta fuera del cuarto: 11:38 AM PMRealizado por/Fecha: J. Vazquez 01-09-20 Verificado por/Fecha: J. Vazquez 01-09-20

TITLE: FORMA PARA REGISTRO PARA CICLO DE ESTERILIZACION

Ciclo de Esterilización:

 Full Cycle (Soft Cycle 125) Half Cycle (Soft Cycle 126) Seleccionado por/Fecha: S.A.S 01-09-20Verificado por/Fecha: J.V. 01-09-20

Verificación de Utilidades:

Utilidades	Parámetro	A	R	N/A	Realizado por / Fecha	Verificado por / Fecha
Nivel de agua en radiador bomba de vacío (BOC EDWARDS)	En el cuello del radiador	/			S.A.S 01-09-20	J.V. 01-09-20
Presión de agua en la Cámara	15 psi ± 5	/			S.A.S 01-09-20	J.V. 01-09-20
Agua caliente en la cámara "Jacket Temperatura"	130 F ± 3	/			S.A.S 01-09-20	J.V. 01-09-20
Sistema de "LEL's"	Alarmas no activadas	/			S.A.S 01-09-20	J.V. 01-09-20
Sistema de "Scrubber"	"OK To Run"	/			S.A.S 01-09-20	J.V. 01-09-20
Agua de enfriamiento	(47 - 54) F	/			S.A.S 01-09-20	J.V. 01-09-20
Vapor de Agua	75 psi - 10	/			S.A.S 01-09-20	J.V. 01-09-20
Aire Comprimido	100 psi - 30	/			S.A.S 01-09-20	J.V. 01-09-20
Papel en la Impresora	Papel alineado en la parte superior	/			S.A.S 01-09-20	J.V. 01-09-20
Bomba (TRAVAINI)	Verificar nivel de Aceite			/	S.A.S 01-09-20	J.V. 01-09-20
Tanque de ETO a Tierra	Cable de tierra conectado al tanque	/			S.A.S 01-09-20	J.V. 01-09-20
Cantidad de ETO	Sobre 80 lb.	/			S.A.S 01-09-20	J.V. 01-09-20
Válvulas de ETO	Deben estar abiertas	/			S.A.S 01-09-20	J.V. 01-09-20
Temperatura "volatilizador"	180 F ± 10	/			S.A.S 01-09-20	J.V. 01-09-20

A= Cumplimiento de parámetro establecido. R= No se cumple con el parámetro establecido.

TANQUE DE ETO A

TANQUE DE ETO B

A. Num. Tanque: E004567
 B. Fecha de Llenado: 09-11-19
 C. Fecha de Expiración: 01-09-20

A. Num. Tanque: E000519
 B. Fecha de Llenado: 10-19-19
 C. Fecha de Expiración: 02-11-20

D. Fecha de Vencimiento
Calibración
Balanza de ETO

11/120
Mes/Año

Realizado por/
Fecha:

S.A.S 01-09-20

Verificado por/
Fecha:

J.V.
01-09-20

E. Peso de Comienzo

982.5 lbs.

Realizado por/
Fecha:

S.A.S 01-09-20

Verificado por/
Fecha:

J.V.
01-09-20

F. Peso de Terminación

922.0 lbs.

Realizado por/
Fecha:

S.A.S 01-09-20

Verificado por/
Fecha:

J.V.
01-09-20

G. Dosis de Gas (D-E)

60.5 lbs.

Realizado por/
Fecha:

S.A.S 01-09-20

Verificado por/
Fecha:

J.V.
01-09-20

Tanques Utilizados:

TANQUE DE ETO A

TANQUE DE ETO B

H. Verificado por QA/Fecha:

(1) Fecha Incorrecta S.A.S 01-09-20

TITLE: FORMA PARA REGISTRO PARA CICLO DE ESTERILIZACION**Ciclo de Esterilización**

~Cámara Cargada: Realizado por/Fecha: J.A 01-09-20

Puerta de Carga Cerrada (Hora): 10:46 AM PM

Realizado por/Fecha: J.A 01-09-20 Verificado por/Fecha: J.A 01-09-20

~Comienzo de ciclo (Hora): 11:48 AM PM

Realizado por/Fecha: J.A 01-09-20 Verificado por/Fecha: J.A 01-09-20

~Puerta de esterilizadora abierta 6" por un mínimo 30 minutos (Hora): 08:08 AM PM

(Hora) Remoción de ciclo: 08:46 AM PM

Realizado por/Fecha: J.A 01-09-20 Verificado por/Fecha: J.A 01-09-20

Etapa De Aireación

Puerta de cámara de aireación abierta (Hora): 08:13 AM PM

(Luego de abrir la puerta del cuarto de aereación, esperar no menos de 10 minutos para entrar al mismo.)

Realizado por/Fecha: J.A 01-09-20 Verificado por/Fecha: J.A 01-09-20

Comienzo de Etapa de Aireación y Remoción de Indicadores Biológicos

(Nota: Remover Indicadores Biológicos mientras mueve paletas a cuarto de aireación.)

Realizado por/Fecha: J.A 01-09-20 Hora: 08:57 AM PM

Verificado por/Fecha: J.A 01-09-20

Finalización de Etapa

Verifique los parámetros, gráfica y tiempo de exposición son aceptables: Temperatura: 125° F +/-10

Tiempo de exposición mínimo para los productos es de: 24 horas

SI NO - Hora de transferido de la 1ra paleta fuera del cuarto: _____ AM PM

Realizado por/Fecha: _____ Verificado por fecha: _____

Auditado por/Fecha: _____

Aprobado por (QA)/Fecha: _____

Empty cycle with ETO
01-09-2020

@E
DATE 01/09/20 Thu
RUN ID # Empty Chamber

CYCLE 125

PROGRAM VERSION 4E-2 CHECK VALUE 13180
OPERATOR A.Alicea

Customed Inc.
W/ETO

COPY

PROCESS PARAMETERS

CHAMBER TEMP 130 F, LO TOL 10 F, HI TOL 10 F, ABORT 165 F
 INITIAL EVACUATION A 7.0 INHGA, 2.01 INHG/MIN
 HUMIDITY INJECTION A 1.0 INHG
 NITROGEN BLANKET A 25.0 INHGA, 1.00 INHG/MIN
 NITROGEN DILUTION 2 CYCLES, RH 0:30 HH:MM, 55 % RH, UPPER 25.0 INHGA, LOWER 22.0 INHGA
 INITIAL EVACUATION B 7.0 INHGA, 2.01 INHG/MIN
 HUMIDITY INJECTION B 1.0 INHG
 HUMIDITY DWELL 1:05 HH:MM, 8.0 INHGA, LO 7.5 INHGA, HI 8.5 INHGA, MAX 9.0 INHGA
 STERILANT INJECTION 19.5 INHGA, 0.71 INHG/MIN
 EXPOSURE 3:05 HH:MM, 19.5 INHGA, LO 19.0 INHGA, HI 20.0 INHGA, ABORT 21.5 INHGA
 LO 5 F, HI 5 F, ABORT 145 F, MAKEUPS: STERILANT
 STERILANT REMOVAL EXHAUST 0.0 SKIP, EVACUATION 7.0 INHGA, 2.01 INHG/MIN
 NITROGEN WASH 3 CYCLES, EVAC DWELL 0:00 HH:MM, UPPER 20.0 INHGA, LOWER 7.0 INHGA
 AIR WASH A 3 CYCLES, EVAC DWELL 0:00 HH:MM, UPPER 20.0 INHGA, LOWER 7.0 INHGA
 FINAL AIRBREAK 27.0 INHGA, 2.01 INHG/MIN

E	TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
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INITIAL EVACUATION A PHASE

E 05:16	134 F	29.8 INHGA	18 %	103 F	
E 05:18	132 F	25.8 INHGA	16 %	103 F	
E 05:20	130 F	21.7 INHGA	14 %	103 F	
E 05:22	129 F	17.7 INHGA	12 %	104 F	
E 05:24	129 F	13.9 INHGA	10 %	104 F	
E 05:26	129 F	10.6 INHGA	7 %	104 F	
E 05:26	129 F	10.5 INHGA	7 %	104 F	SLOW INCREMENT
E 05:28	129 F	8.2 INHGA	6 %	104 F	
E 05:29	129 F	7.0 INHGA	5 %	104 F	

MAX:	134 F	-22.8 INHG	18 %	PHASE 0:13	PHASE ELAPSED 0:13
MIN:	129 F	(CHANGE)	5 %	CYCLE 0:13	

HUMIDITY INJECTION A (PRESS) PHASE

E 05:29	129 F	7.0 INHGA	5 %	104 F
E 05:29	129 F	8.0 INHGA	9 %	106 F

MAX:	129 F	1.0 INHG	9 %	PHASE 0:00	PHASE ELAPSED 0:00
MIN:	129 F	(CHANGE)	5 %	CYCLE 0:13	

E01/09/20 Thu CYCLE 125

RUN ID # Empty Chamber

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
NITROGEN BLANKET A PHASE						
E 05:29	129 F	8.1 INHG	9 %	106 F		
E 05:31	132 F	10.2 INHG	42 %	107 F		
E 05:33	134 F	12.2 INHG	43 %	109 F		
E 05:35	134 F	14.2 INHG	44 %	112 F		
E 05:37	135 F	16.2 INHG	44 %	114 F		
E 05:39	135 F	18.2 INHG	45 %	115 F		
E 05:41	135 F	20.2 INHG	45 %	116 F		
E 05:43	135 F	22.2 INHG	45 %	117 F		
E 05:45	135 F	24.2 INHG	45 %	118 F		
E 05:45	135 F	25.0 INHG	45 %	118 F		
MAX:	135 F	17.0 INHG	45 %		PHASE 0:16	PHASE ELAPSED 0:16
MIN:	129 F	(CHANGE)	9 %		CYCLE	0:29

COPY

NITROGEN DILUTION (WASH) PHASE

E 05:45	135 F	25.0 INHG	45 %	118 F		
E 05:45	135 F	25.0 INHG	45 %	118 F	BEGIN RH	1
E 05:47	135 F	27.0 INHG	73 %	116 F		
E 05:49	135 F	26.8 INHG	81 %	115 F		
E 05:51	134 F	26.8 INHG	83 %	114 F		
E 05:53	134 F	26.8 INHG	85 %	113 F		
E 05:55	134 F	26.8 INHG	87 %	113 F		
E 05:57	134 F	26.8 INHG	88 %	112 F		
E 05:59	133 F	26.8 INHG	89 %	112 F		
E 06:01	133 F	26.8 INHG	90 %	112 F		
E 06:03	133 F	26.8 INHG	91 %	111 F		
E 06:05	133 F	26.8 INHG	91 %	111 F		
E 06:07	133 F	26.8 INHG	92 %	111 F		
E 06:09	133 F	26.8 INHG	93 %	111 F		
E 06:11	133 F	26.8 INHG	94 %	110 F		
E 06:13	133 F	26.8 INHG	94 %	110 F		
E 06:15	133 F	26.8 INHG	95 %	110 F		
E 06:15	133 F	26.8 INHG	95 %	110 F	BEGIN NITROGEN	1
E 06:15	133 F	26.8 INHG	95 %	110 F	BEGIN EVACUATION	1
E 06:17	131 F	22.8 INHG	85 %	111 F		
E 06:18	131 F	22.0 INHG	85 %	111 F	BEGIN RH	2
E 06:19	131 F	22.2 INHG	85 %	110 F		
E 06:21	132 F	22.2 INHG	85 %	110 F		
E 06:23	132 F	22.2 INHG	85 %	110 F		
E 06:25	132 F	22.3 INHG	86 %	109 F		
E 06:27	132 F	22.3 INHG	86 %	109 F		
E 06:29	132 F	22.3 INHG	86 %	109 F		
E 06:31	132 F	22.3 INHG	87 %	109 F		
E 06:33	132 F	22.4 INHG	87 %	109 F		
E 06:35	132 F	22.4 INHG	88 %	109 F		
E 06:37	132 F	22.4 INHG	88 %	109 F		
E 06:39	132 F	22.4 INHG	89 %	109 F		
E 06:41	132 F	22.4 INHG	89 %	109 F		
E 06:43	132 F	22.4 INHG	89 %	109 F		
E 06:45	132 F	22.4 INHG	90 %	109 F		
E 06:47	132 F	22.4 INHG	90 %	109 F		

E01/09/20 Thu

CYCLE 125

RUN ID # Empty Chamber

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
E 06:48	132 F	22.4 INHG	90 %	109 F		BEGIN NITROGEN 2
E 06:49	133 F	24.7 INHG	91 %	112 F		
E 06:50	133 F	25.0 INHG	91 %	112 F		BEGIN EVACUATION 2
E 06:51	132 F	22.0 INHG	83 %	111 F		
E 06:51	132 F	22.0 INHG	83 %	111 F		
MAX:	135 F	-3.0 INHG	95 %		PHASE 1:06	PHASE ELAPSED 1:06
MIN:	131 F	(CHANGE)	45 %			CYCLE 1:36

INITIAL EVACUATION B PHASE

E 06:52	132 F	21.9 INHG	83 %	111 F		COPY
E 06:54	130 F	17.9 INHG	71 %	110 F		
E 06:56	128 F	14.0 INHG	60 %	110 F		
E 06:58	128 F	10.8 INHG	49 %	109 F		
E 06:58	128 F	10.7 INHG	49 %	109 F	SLOW INCREMENT	
E 07:00	128 F	8.3 INHG	41 %	109 F		
E 07:01	128 F	7.0 INHG	36 %	109 F		
MAX:	132 F	-15.0 INHG	83 %		PHASE 0:09	PHASE ELAPSED 0:09
MIN:	128 F	(CHANGE)	36 %			CYCLE 1:45

HUMIDITY INJECTION B (PRESS) PHASE

E 07:01	128 F	7.0 INHG	36 %	109 F		
E 07:01	128 F	8.0 INHG	39 %	111 F		
MAX:	128 F	1.0 INHG	39 %		PHASE 0:00	PHASE ELAPSED 0:00
MIN:	128 F	(CHANGE)	36 %			CYCLE 1:45

HUMIDITY DWELL (PRESS) PHASE

E 07:01	128 F	8.1 INHG	39 %	111 F	
E 07:02	129 F	8.5 INHG	50 %	121 F	HI HUMIDITY
E 07:03	131 F	8.6 INHG	71 %	122 F	
E 07:05	131 F	8.7 INHG	72 %	119 F	
E 07:07	131 F	8.7 INHG	74 %	117 F	
E 07:09	131 F	8.8 INHG	75 %	116 F	
E 07:11	132 F	8.8 INHG	76 %	115 F	
E 07:13	132 F	8.8 INHG	77 %	114 F	
E 07:15	132 F	8.9 INHG	78 %	113 F	
E 07:17	132 F	8.9 INHG	78 %	112 F	
E 07:19	132 F	8.9 INHG	79 %	112 F	
E 07:21	132 F	9.0 INHG	80 %	111 F	
E 07:23	131 F	9.0 INHG	80 %	111 F	MAXIMUM HUMIDITY
E 07:23	131 F	9.0 INHG	80 %	111 F	
E 07:25	131 F	9.0 INHG	81 %	110 F	
E 07:27	131 F	9.0 INHG	81 %	110 F	
E 07:29	131 F	9.1 INHG	82 %	109 F	
E 07:31	131 F	9.1 INHG	82 %	109 F	

E01/09/20 Thu

CYCLE 125

RUN ID # Empty Chamber

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
E 07:33	131 F	9.1 INHG	83 %	109 F		
E 07:35	131 F	9.1 INHG	83 %	109 F		
E 07:37	131 F	9.1 INHG	84 %	108 F		
E 07:39	131 F	9.1 INHG	84 %	109 F		
E 07:41	131 F	9.1 INHG	84 %	108 F		
E 07:43	131 F	9.2 INHG	85 %	108 F		
E 07:45	131 F	9.2 INHG	85 %	108 F		
E 07:47	131 F	9.2 INHG	85 %	108 F		
E 07:49	131 F	9.2 INHG	86 %	108 F		
E 07:51	131 F	9.2 INHG	86 %	108 F		
E 07:53	131 F	9.2 INHG	86 %	108 F		
E 07:55	131 F	9.2 INHG	87 %	108 F		
E 07:57	131 F	9.2 INHG	87 %	108 F		
E 07:59	131 F	9.2 INHG	87 %	108 F		
E 08:01	131 F	9.2 INHG	88 %	108 F		
E 08:03	131 F	9.2 INHG	88 %	108 F		
E 08:05	131 F	9.3 INHG	88 %	108 F		
E 08:06	131 F	9.3 INHG	88 %	108 F		
MAX:	132 F	1.2 INHG	88 %		PHASE	1:05
MIN:	128 F	(CHANGE)	39 %		CYCLE	2:50

COPY

STERILANT INJECTION PHASE

E 08:06	131 F	9.3 INHG	88 %	108 F
E 08:08	131 F	10.8 INHG	96 %	113 F
E 08:10	132 F	11.8 INHG	97 %	116 F
E 08:11	132 F	11.9 INHG	94 %	115 F SLOW INCREMENT

EGROSS =1011.1 LB

, USING DRUM A

CYCLE STOP

EGROSS =1011.1 LB

, USING DRUM B

EXIT SCALE COMMAND

E 08:12	131 F	12.0 INHG	90 %	114 F	
E 08:13	131 F	12.0 INHG	88 %	114 F	CYCLE CONTINUED
E 08:14	131 F	13.7 INHG	92 %	113 F	
E 08:16	132 F	15.1 INHG	95 %	114 F	
E 08:18	132 F	16.5 INHG	96 %	115 F	
E 08:20	132 F	17.9 INHG	97 %	116 F	
E 08:22	132 F	19.3 INHG	96 %	117 F	
E 08:23	132 F	19.5 INHG	96 %	117 F	

MAX: 132 F 10.2 INHG 97 % PHASE 0:16 PHASE ELAPSED 0:16

MIN: 131 F (CHANGE) 88 % CYCLE 3:07

STERILANT USED THIS PHASE: 43.0 LB, CYCLE TOTAL: 43.0 LB

E01/09/20 Thu CYCLE 125

RUN ID # Empty Chamber

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
EXPOSURE PHASE						
E 08:23	132 F	19.7 INHG	96 %	118 F		
E 08:25	132 F	19.6 INHG	90 %	115 F		
E 08:27	131 F	19.6 INHG	90 %	114 F		
E 08:29	131 F	19.6 INHG	91 %	114 F		
E 08:31	130 F	19.6 INHG	92 %	113 F		
E 08:33	130 F	19.6 INHG	92 %	113 F		
E 08:35	130 F	19.6 INHG	92 %	112 F		
E 08:37	130 F	19.6 INHG	93 %	112 F		
E 08:39	130 F	19.7 INHG	93 %	111 F		
E 08:41	130 F	19.7 INHG	93 %	111 F		
E 08:43	130 F	19.7 INHG	94 %	111 F		
E 08:45	130 F	19.7 INHG	94 %	111 F		
E 08:47	130 F	19.7 INHG	94 %	110 F		
E 08:49	130 F	19.7 INHG	94 %	110 F		
E 08:51	130 F	19.7 INHG	95 %	110 F		
E 08:53	130 F	19.7 INHG	95 %	110 F		
E 08:55	130 F	19.7 INHG	95 %	110 F		
E 08:57	130 F	19.7 INHG	95 %	110 F		
E 08:58	130 F	19.7 INHG	95 %	110 F		OPERATOR CYCLE ABORT
E 08:58	130 F	19.7 INHG	95 %	110 F	SHORT EXPOSURE	
E 08:58	130 F	19.7 INHG	95 %	110 F		
MAX:	132 F	0.0 INHG	96 %		PHASE 0:34	PHASE ELAPSED 0:34
MIN:	130 F	(CHANGE)	90 %		CYCLE 3:42	

COPY

STERILANT REMOVAL PHASE						
E 08:58	130 F	19.7 INHG	95 %	110 F		
E 08:58	130 F	19.7 INHG	95 %	110 F	BEGIN EVACUATION	
E 09:00	129 F	15.6 INHG	85 %	110 F		
E 09:02	127 F	12.1 INHG	72 %	110 F		
E 09:03	127 F	10.5 INHG	65 %	109 F	SLOW INCREMENT	
E 09:04	127 F	9.3 INHG	60 %	109 F		
E 09:06	127 F	7.2 INHG	50 %	108 F		
E 09:06	127 F	7.0 INHG	49 %	108 F		
MAX:	130 F	-12.7 INHG	95 %		PHASE 0:08	PHASE ELAPSED 0:08
MIN:	127 F	(CHANGE)	49 %		CYCLE 3:50	

NITROGEN WASH (WASH) PHASE						
E 09:06	127 F	7.0 INHG	49 %	108 F		
E 09:06	127 F	7.0 INHG	49 %	108 F	BEGIN NITROGEN	1
E 09:08	129 F	9.1 INHG	49 %	107 F		
E 09:10	130 F	11.1 INHG	48 %	108 F		
E 09:12	131 F	13.1 INHG	47 %	110 F		
E 09:14	132 F	15.1 INHG	47 %	113 F		
E 09:16	132 F	17.1 INHG	47 %	114 F		
E 09:18	132 F	19.1 INHG	47 %	115 F		
E 09:18	132 F	20.0 INHG	47 %	115 F	BEGIN EVACUATION	1

E01/09/20 Thu CYCLE 125

RUN ID # Empty Chamber

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
E 09:20	130 F	16.8 INHG	42 %	115 F		
E 09:22	128 F	13.1 INHG	36 %	114 F		
E 09:23	127 F	10.7 INHG	31 %	113 F	SLOW INCREMENT	
E 09:24	127 F	10.0 INHG	30 %	113 F		
E 09:26	127 F	7.7 INHG	25 %	112 F		
E 09:27	127 F	7.0 INHG	23 %	112 F		BEGIN NITROGEN 2
E 09:28	128 F	8.6 INHG	23 %	110 F		
E 09:30	130 F	10.6 INHG	22 %	110 F		
E 09:32	131 F	12.6 INHG	22 %	111 F		
E 09:34	132 F	14.6 INHG	22 %	113 F		
E 09:36	132 F	16.6 INHG	21 %	115 F		
E 09:38	132 F	18.6 INHG	21 %	116 F		
E 09:39	132 F	20.0 INHG	21 %	116 F		BEGIN EVACUATION 2
E 09:40	132 F	17.8 INHG	20 %	117 F		
E 09:42	129 F	14.3 INHG	17 %	115 F		
E 09:44	127 F	10.9 INHG	14 %	115 F		
E 09:44	127 F	10.6 INHG	14 %	115 F	SLOW INCREMENT	
E 09:46	127 F	8.4 INHG	11 %	114 F		
E 09:47	127 F	7.0 INHG	10 %	114 F		BEGIN NITROGEN 3
E 09:48	128 F	8.2 INHG	10 %	110 F		
E 09:50	130 F	10.2 INHG	10 %	109 F		
E 09:52	131 F	12.2 INHG	9 %	110 F		
E 09:54	131 F	14.2 INHG	9 %	113 F		
E 09:56	132 F	16.2 INHG	9 %	115 F		
E 09:58	132 F	18.3 INHG	9 %	116 F		
E 10:00	132 F	20.0 INHG	9 %	117 F		BEGIN EVACUATION 3
E 10:00	132 F	19.7 INHG	9 %	117 F		
E 10:02	130 F	15.7 INHG	7 %	117 F		
E 10:04	128 F	11.9 INHG	6 %	116 F		
E 10:05	127 F	10.6 INHG	6 %	115 F	SLOW INCREMENT	
E 10:06	127 F	9.1 INHG	5 %	115 F		
E 10:08	127 F	7.0 INHG	4 %	114 F		
MAX:	132 F	0.0 INHG	49 %		PHASE 1:01	PHASE ELAPSED 1:01
MIN:	127 F	(CHANGE)	4 %		CYCLE 4:52	

COPY

AIR WASH A (WASH) PHASE

E 10:08	127 F	7.0 INHG	4 %	114 F		
E 10:08	127 F	7.0 INHG	4 %	114 F		BEGIN INBLEED 1
E 10:10	131 F	11.4 INHG	6 %	114 F		
E 10:12	133 F	15.4 INHG	8 %	113 F		
E 10:14	133 F	19.3 INHG	10 %	113 F		
E 10:14	133 F	20.1 INHG	10 %	113 F		BEGIN EVACUATION 1
E 10:16	131 F	16.2 INHG	9 %	112 F		
E 10:18	128 F	12.7 INHG	8 %	112 F		
E 10:19	128 F	10.7 INHG	7 %	112 F	SLOW INCREMENT	
E 10:20	127 F	9.7 INHG	6 %	112 F		
E 10:22	127 F	7.5 INHG	5 %	111 F		
E 10:22	127 F	7.0 INHG	4 %	111 F		BEGIN INBLEED 2
E 10:24	130 F	11.7 INHG	6 %	111 F		
E 10:26	132 F	15.7 INHG	8 %	111 F		
E 10:28	133 F	19.6 INHG	10 %	110 F		
E 10:29	134 F	20.1 INHG	11 %	110 F		BEGIN EVACUATION 2



E01/09/20 Thu CYCLE 125

RUN ID # Empty Chamber

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
E 10:30	132 F	17.7 INHG	10 %	110 F		
E 10:32	129 F	13.7 INHG	9 %	110 F		
E 10:34	128 F	10.7 INHG	7 %	110 F	SLOW INCREMENT	
E 10:34	128 F	10.5 INHG	7 %	110 F		
E 10:36	127 F	8.1 INHG	5 %	110 F		
E 10:37	127 F	7.0 INHG	5 %	110 F		BEGIN INBLEED 3
E 10:38	129 F	9.5 INHG	6 %	110 F		
E 10:40	133 F	13.4 INHG	8 %	110 F		
E 10:42	133 F	17.4 INHG	10 %	110 F		
E 10:43	133 F	20.1 INHG	11 %	110 F		BEGIN EVACUATION 3
E 10:44	133 F	18.4 INHG	11 %	110 F		
E 10:46	130 F	14.7 INHG	9 %	110 F		
E 10:48	128 F	11.3 INHG	7 %	110 F		
E 10:48	128 F	10.7 INHG	7 %	110 F	SLOW INCREMENT	
E 10:50	127 F	8.6 INHG	6 %	110 F		
E 10:51	127 F	7.0 INHG	5 %	110 F		
MAX:	134 F	0.0 INHG	11 %		PHASE 0:43	PHASE ELAPSED 0:43
MIN:	127 F	(CHANGE)	4 %			CYCLE 5:35

COPY

FINAL AIRBREAK PHASE

E 10:51	127 F	7.0 INHG	5 %	110 F		
E 10:53	131 F	11.4 INHG	7 %	109 F		
E 10:55	133 F	15.3 INHG	9 %	109 F		
E 10:57	134 F	19.3 INHG	11 %	110 F		
E 10:59	134 F	23.2 INHG	13 %	110 F		
E 11:01	134 F	27.0 INHG	15 %	109 F		
MAX:	134 F	20.0 INHG	15 %		PHASE 0:09	PHASE ELAPSED 0:09
MIN:	127 F	(CHANGE)	5 %			CYCLE 5:45

END OF CYCLE PHASE

11:01

TOTAL CYCLE 5:44 CYCLE ELAPSED 5:45

OPERATOR _____

ACCEPT _____ NON CONFORMANCE _____

Q.A. _____ DATE _____
SUPERVISOR _____

Empty Chamber with ETO

01-09-2020

Samples taken for SCV testing

STERILIZATION PROCEDURE (STP)

Issued by: GD24-J- Title: QA/Doc. Control Date: 06-06-19
Approved by: N. Munoz Title: QA Director Date: 06-14-19

TITLE: FORMA PARA REGISTRO PARA CICLO DE ESTERILIZACION**PARA USO DEL DEPARTAMENTO DE CALIDAD**Num. de Lote de Carga SL # Empty cycle with ETO01/09/2020

Para Productos: Ver Forma STP 002-03

Procedimiento Etapa de Pre-acondicionamiento:

STP 003

Procedimiento Proceso de Esterilización:

STP 002 , STP 010

Procedimiento Etapa de Aireación:

STP 004 Full Cycle (Soft Cycle 125) Ciclo contiene productos a ser re-esterilizados (Soft Cycle 125) Validation Half Cycle (Soft Cycle 126)**COPY**

BI's Lot # _____, expiration date: _____

Cantidad de BI's Utilizados: _____ + (Control positivo: 1 BI) = _____ Total: _____

Documento Completado y BI's Ubicados por/Fecha: _____

Verificado por/Fecha: _____

Etapa de Pre – Acondicionamiento**Comienzo de Etapa de Pre Acondicionamiento**Realizado por/Fecha: _____ Hora: _____ AM PM

Verificado por/Fecha: _____

I.A
01-09-20**Finalización de Etapa de Pre Acondicionamiento**

Verifique y marque con marca de cotejo (Si o No) que los parámetros de temperatura y humedad relativa y tiempo de exposición son aceptables:

Parámetros de ciclo 125 (Soft cycle): Temperatura: **115° F ± 9°F**, Humedad: **65%RH ± 15%RH**, Tiempo exposición mínimo a parámetros de temperatura/ humedad: **12 horas**.Parámetros aceptables: **SI NO** Hora de transferencia de la 1ra paleta fuera del cuarto: _____ AM PM

Realizado por/Fecha: _____ Verificado por/Fecha: _____

TITLE: FORMA PARA REGISTRO PARA CICLO DE ESTERILIZACION

Ciclo de Esterilización:

Full Cycle (Soft Cycle 125) Half Cycle (Soft Cycle 126) Seleccionado por/Fecha: J.A 01-09-20

Verificado por/Fecha: J.A 01-09-20

Verificación de Utilidades:

Utilidades	Parámetro	A	R	N/A	Realizado por / Fecha	Verificado por / Fecha
Nivel de agua en radiador bomba de vacío (BOC EDWARDS)	En el cuello del radiador	/			<u>J.A 01-09-20</u>	<u>J.A 01-09-20</u>
Presión de agua en la Cámara	15 psi ± 5	/			<u>J.A 01-09-20</u>	<u>J.A 01-09-20</u>
Agua caliente en la cámara "Jacket Temperatura"	130 F ± 3	/			<u>J.A 01-09-20</u>	<u>J.A 01-09-20</u>
Sistema de "LEL's "	Alarmas no activadas	/			<u>J.A 01-09-20</u>	<u>J.A 01-09-20</u>
Sistema de "Scrubber"	"OK To Run"	/			<u>J.A 01-09-20</u>	<u>J.A 01-09-20</u>
Agua de enfriamiento	(47 - 54) F	/			<u>J.A 01-09-20</u>	<u>J.A 01-09-20</u>
Vapor de Agua	75 psi - 10	/			<u>J.A 01-09-20</u>	<u>J.A 01-09-20</u>
Aire Comprimido	100 psi - 30	/			<u>J.A 01-09-20</u>	<u>J.A 01-09-20</u>
Papel en la Impresora	Papel alineado en la parte superior	/			<u>J.A 01-09-20</u>	<u>J.A 01-09-20</u>
Bomba (TRAVAINI)	Verificar nivel de Aceite			/	<u>J.A 01-09-20</u>	<u>J.A 01-09-20</u>
Tanque de ETO a Tierra	Cable de tierra conectado al tanque	/			<u>J.A 01-09-20</u>	<u>J.A 01-09-20</u>
Cantidad de ETO	Sobre 80 lb.	/			<u>J.A 01-09-20</u>	<u>J.A 01-09-20</u>
Válvulas de ETO	Deben estar abiertas	/			<u>J.A 01-09-20</u>	<u>J.A 01-09-20</u>
Temperatura "volatilizador"	180 F ± 10	/			<u>J.A 01-09-20</u>	<u>J.A 01-09-20</u>

A= Cumplimiento de parámetro establecido.

R= No se cumple con el parámetro establecido.

TANQUE DE ETO A		TANQUE DE ETO B	
A. Num. Tanque:	<u>E004567</u>	A. Num. Tanque:	<u>G000519</u>
B. Fecha de Llenado:	<u>09-11-19</u>	B. Fecha de Llenado:	<u>10-14-19</u>
C. Fecha de Expiración:	<u>01-09-20</u>	C. Fecha de Expiración:	<u>02-11-20</u>
D. Fecha de Vencimiento Calibración Balanza de ETO	<u>11/120</u> Mes/Año	Realizado por/ Fecha: <u>J.A 01-09-20</u>	Verificado por/ Fecha: <u>J.A 01-09-20</u>
E. Peso de Comienzo	<u>1,025.5 lbs.</u>	Realizado por/ Fecha: <u>J.A 01-09-20</u>	Verificado por/ Fecha: <u>J.A 01-09-20</u>
F. Peso de Terminación	<u>982.5 lbs.</u>	Realizado por/ Fecha: <u>J.A 01-09-20</u>	Verificado por/ Fecha: <u>J.A 01-09-20</u>
G. Dosis de Gas (D-E)	<u>43.0 lbs.</u>	Realizado por/ Fecha: <u>J.A 01-09-20</u>	Verificado por/ Fecha: <u>J.A 01-09-20</u>
Tanques Utilizados:	<input checked="" type="checkbox"/>	TANQUE DE ETO A	TANQUE DE ETO B
H. Verificado por QA/Fecha:			

TITLE: FORMA PARA REGISTRO PARA CICLO DE ESTERILIZACION**Ciclo de Esterilización**

~Cámara Cargada: Realizado por/Fecha: _____

Puerta de Carga Cerrada (Hora): _____ AM PM

Realizado por/Fecha: _____ Verificado por/Fecha: _____

30 01-09-20

~Comienzo de ciclo (Hora): _____ AM PM

Realizado por/Fecha: _____ Verificado por/Fecha: _____

30 01-09-20

~Puerta de esterilizadora abierta 6" por un mínimo 30 minutos (Hora): 11:02 AM PM

(Hora) Remoción de ciclo: _____ AM PM

Realizado por/Fecha: SA 01-09-20 Verificado por/Fecha: SA 01-09-20

Etapa De Aireación ① Puerta cerrada a las 11:35 A.M. SA 01-09-20

Puerta de cámara de aireación abierta (Hora): _____ AM PM

(Luego de abrir la puerta del cuarto de aereación, esperar no menos de 10 minutos para entrar al mismo.)

Realizado por/Fecha: _____ Verificado por/Fecha: _____

Comienzo de Etapa de Aireación y Remoción de Indicadores Biológicos

(Nota: Remover Indicadores Biológicos mientras mueve paletas a cuarto de aireación.)

Realizado por/Fecha: SA 01-09-20 Hora: 11:35 SA 01-09-20 AM PM

Verificado por/Fecha: _____

Finalización de Etapa

Verifique los parámetros, gráfica y tiempo de exposición son aceptables: Temperatura: 125° F +/-10
Tiempo de exposición mínimo para los productos es de: 24 horas

SI NO - Hora de transferido de la 1ra paleta fuera del cuarto: _____ AM PM

Realizado por/Fecha: _____ Verificado por fecha: _____

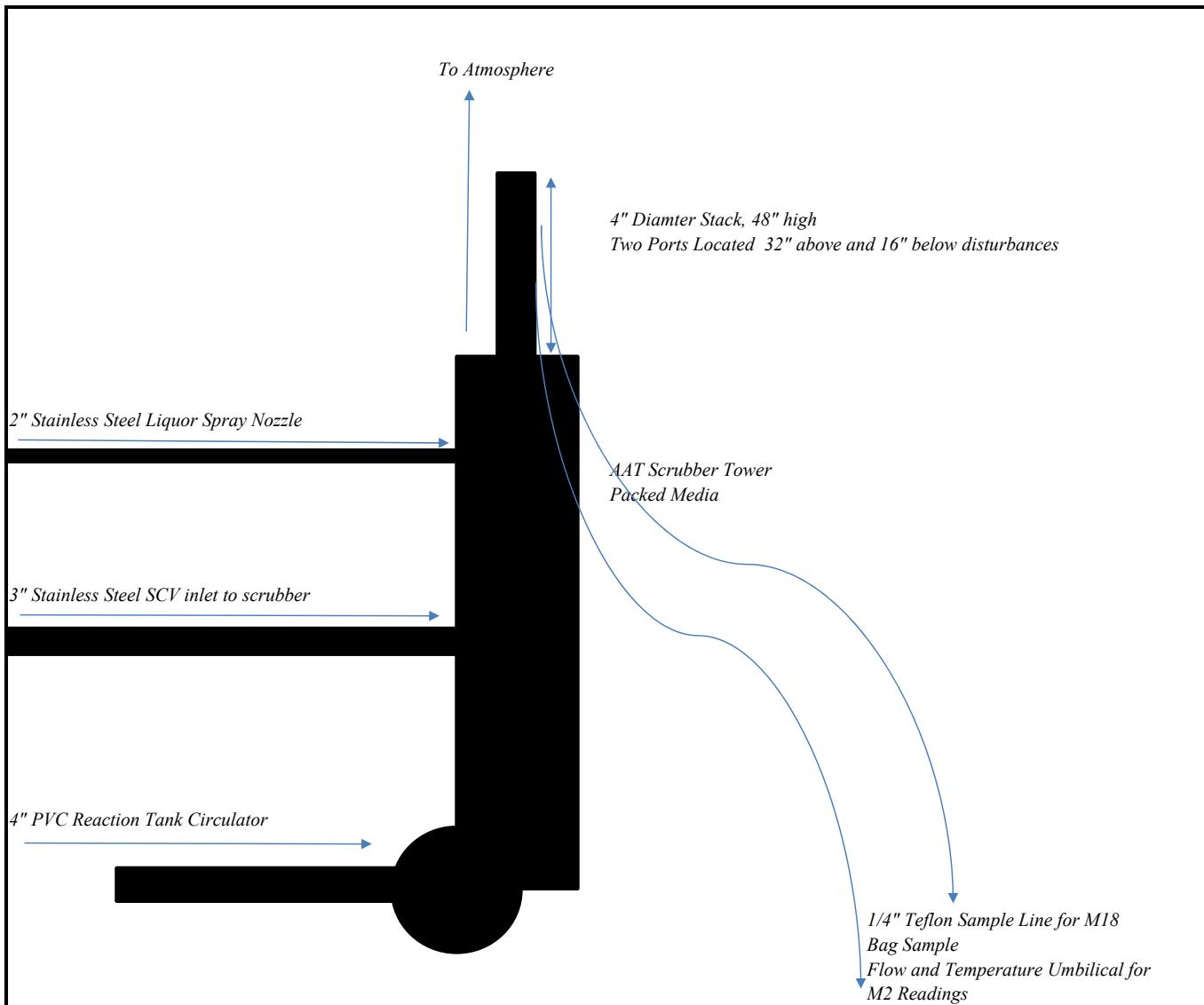
Auditado por/Fecha: _____

Aprobado por (QA)/Fecha: _____

ATTACHMENT G

SCRUBBER SKETCH

Customed, Inc. Fajardo, Puerto Rico
Advanced Air Technologies Acid Gas Scrubber
Stack Drawing



LCH Consulting Associates, LLC

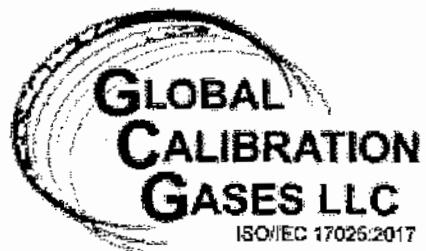
88 Glocker Way PMB 287

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01/28/2020

ATTACHMENT H

CALIBRATION RECORDS



Certificate of Analysis

Certified Standard

Customer: Keen
CGA: 180
Customer PO#: 79633
Cylinder #: CK1551770

Reference#: 120819SY-J
Certification Date: 12/10/2019
Expiration Date: 12/10/2020
Pressure, psig: 1800

Components	Requested Concentration	Certified Concentration	Analytical Accuracy
Ethylene Oxide	5ppm	4.8ppm	± 10%
Nitrogen	Balance	Balance	

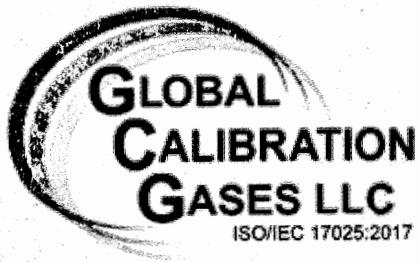
This report states accurately the results of the investigation made upon the material submitted to the analytical laboratory. Every effort has been made to determine objectively the information requested. However, in connection with this report, Global Calibration Gases LLC shall have no liability in excess of the established charge for this service.

Produced by:

Global Calibration Gases LLC:
1090 Commerce Blvd N.
Sarasota, Florida 34243 USA
PGVP Vendor ID.: N22019

Principal Analyst: Karen Walker
Date: 12/10/2019

Principal Reviewer: Jeanett May
Date: 12/10/2019



Certificate of Analysis

Certified Standard

Customer: Keen
CGA: 180
Customer PO#: 79633
Cylinder #: CK1551640

Reference#: 120819SY-G
Certification Date: 12/10/2019
Expiration Date: 12/10/2020
Pressure, psig: 1800

Components	Requested Concentration	Certified Concentration	Analytical Accuracy
Ethylen Oxide	1.0ppm	1.0ppm	± 10%
Nitrogen	Balance	Balance	

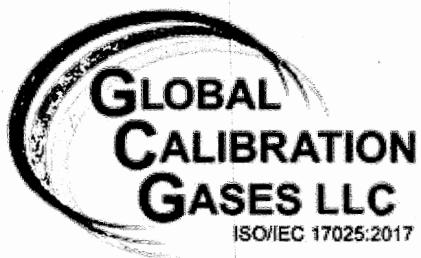
This report states accurately the results of the investigation made upon the material submitted to the analytical laboratory. Every effort has been made to determine objectively the information requested. However, in connection with this report, Global Calibration Gases LLC shall have no liability in excess of the established charge for this service.

Produced by:

Global Calibration Gases LLC,
1090 Commerce Blvd N.
Sarasota, Florida 34243 USA
PGVP Vendor ID.: N22019

Principal Analyst: Kathy Walker
Date: 12/10/2019

Principal Reviewer: Jeanne P. Honey
Date: 12/10/2019



ISO/IEC 17025:2017

Certificate of Analysis

Certified Standard

Customer: Keen
CGA: 180
Customer PO#: 79633
Cylinder #: CK1551650

Reference#: 120819SY-H
Certification Date: 12/10/2019
Expiration Date: 12/10/2020
Pressure, psig: 1800

Components	Requested Concentration	Certified Concentration	Analytical Accuracy
Ethylene Oxide	0.5ppm	0.5ppm	± 20%
Nitrogen	Balance	Balance	

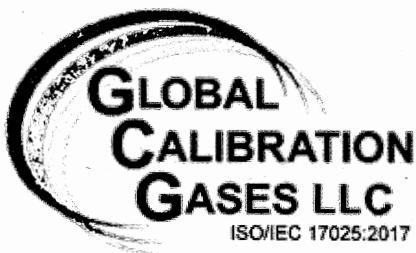
This report states accurately the results of the investigation made upon the material submitted to the analytical laboratory. Every effort has been made to determine objectively the information requested. However, in connection with this report, Global Calibration Gases LLC shall have no liability in excess of the established charge for this service.

Produced by:

Global Calibration Gases LLC.
1090 Commerce Blvd N.
Sarasota, Florida 34243 USA
PGVP Vendor ID.: N22019

Principal Analyst: Kathy Wallen
Date: 12/10/2019

Principal Reviewer: Jenny Honey
Date: 12/10/2019



Certificate of Analysis

Certified Standard

Customer: Keen
CGA: 180
Customer PO#: 79633
Cylinder #: CK1551725

Reference#: 120819SY-I
Certification Date: 12/10/2019
Expiration Date: 12/10/2020
Pressure, psig: 1800

Components	Requested Concentration	Certified Concentration	Analytical Accuracy
Ethylene Oxide	2.5ppm	2.4ppm	± 10%
Nitrogen	Balance	Balance	-

This report states accurately the results of the investigation made upon the material submitted to the analytical laboratory. Every effort has been made to determine objectively the information requested. However, in connection with this report, Global Calibration Gases LLC shall have no liability in excess of the established charge for this service.

Produced by:

Global Calibration Gases LLC.
1090 Commerce Blvd N.
Sarasota, Florida 34243 USA
PGVP Vendor ID.: N22019

Principal Analyst: Kathy Wallen
Date: 12/10/2019

Principal Reviewer: Jeanne Anthony
Date: 12/10/2019



GASCO AFFILIATES, LLC.

320 Scarlet Blvd.
Oldsmar, FL 34677
(800) 910-0051
fax: (866) 755-8920
www.gascogas.com

CERTIFICATE OF ANALYSIS

Date: January 10, 2020

Customer: LGH Consulting Services LLC

Order Number: PO092519

Use Before: 01/10/2021

Lot Number: BCA-X02NI99CA9800B3-1

Component	Specification (+/- 10%)	Analytical Result (+/- 2%)
Ethylene Oxide	1 PPM	1 PPM
Nitrogen	BALANCE	BALANCE

Cylinder Size: 4.0 Cu. Ft.

Valve: CGA 180

Contents: 110 Liter

Pressure: 1500 psig

The calibration gas prepared by Gasco is considered a certified standard. It is prepared by gravimetric, or partial pressure techniques. The calibration standard provided is certified against Gasco's G.M.I.S. (Gas Manufacturer's Intermediate Standard) which is either prepared by weights traceable to the National Institute of Standards and Technology (NIST) or by using NIST Standard Reference Materials where available.

TECHNICAL RECOMMENDATIONS

For best results, use the following procedure when using Reactive Gas Mixtures and always use the shortest length possible of Teflon Tubing between the Cylinder Regulator Hose Barb and the Gas Detection Instrument. Turn the regulator on before connection is made with the cylinder, allowing any trapped air to be purged from the regulator. Be sure to turn the regulator off as soon as the regulator is fully connected. Always ensure delivery tubing is compatible with the Gas. Do not store this cylinder with the regulator installed due to possible leakage or long-term reaction with internal components of the regulator. Follow instrument manufacturer's instruction manual.

Analyst:

Efton Eakins

Afton Eakins



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CERTIFICATE OF ANALYSIS

Date: January 10, 2020

Customer: LGH Consulting Services LLC

Order Number: PO092519

Lot Number: BCA-X02NI99CA9800A6-1

Use Before: 01/10/2021

Component	Specification (+/- 10%)	Analytical Result (+/- 2%)
Ethylene Oxide	5 PPM	5.1 PPM
Nitrogen	BALANCE	BALANCE

Cylinder Size: 4.0 Cu. Ft.
Contents: 110 Liter

Valve: CGA 180
Pressure: 1500 psig

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Analyst:

Afton Eakins

Afton Eakins



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CERTIFICATE OF ANALYSIS

Date: January 10, 2020

Customer: LGH Consulting Services LLC

Order Number: PO092519

Lot Number: BCA-X02NI99CA9800A7-1

Use Before: 01/10/2021

Component	Specification (+/- 10%)	Analytical Result (+/- 2%)
Ethylene Oxide	10 PPM	10.1 PPM
Nitrogen	BALANCE	BALANCE

Cylinder Size: 4.0 Cu. Ft.

Valve: CGA 180

Contents: 110 Liter

Pressure: 1500 psig

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Analyst:

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Afton Eakins



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CERTIFICATE OF ANALYSIS

Date: January 10, 2020

Customer: LGH Consulting Services LLC

Order Number: PO092519

Lot Number: BCA-X02NI99CA9800A9-1

Use Before: 01/10/2021

Component	Specification (+/- 5%)	Analytical Result (+/- 2%)
Ethylene Oxide	100 PPM	100.2 PPM
Nitrogen	BALANCE	BALANCE

Cylinder Size: 4.0 Cu. Ft.

Valve: CGA 180

Contents: 110 Liter

Pressure: 1500 psig

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Analyst:

Afton Eakins

Afton Eakins



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CERTIFICATE OF ANALYSIS

Date: January 10, 2020

Order Number: PO092519

Lot Number: BCA-X02NI99CA9800B1-1

Customer: LGH Consulting Services LLC

Use Before: 01/10/2021

Component	Specification (+/- 5%)	Analytical Result (+/- 2%)
Ethylene Oxide	1000 PPM	990 PPM
Nitrogen	BALANCE	BALANCE

Cylinder Size: 4.0 Cu. Ft.

Contents: 110 Liter

Valve: CGA 180

Pressure: 1500 psig

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Afton Eakins



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CERTIFICATE OF ANALYSIS

Date: January 10, 2020

Customer: LGH Consulting Services LLC

Order Number: PO092519

Lot Number: BCA-X02NI99CA9800B2-1

Use Before: 01/10/2021

Component	Specification (+/- 5%)	Analytical Result (+/- 2%)
Ethylene Oxide	5000 PPM	5000 PPM
Nitrogen	BALANCE	BALANCE

Cylinder Size: 4.0 Cu. Ft.

Valve: CGA 180

Contents: 110 Liter

Pressure: 1500 psig

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